CHAPTER III

RESULTS

Physical Properties of Durian Rind Extract (D_1,D_2) and Various Disintegrants

(a) Particle Size and Shape

Photomicrographs of various disintegrants in different magnification are shown in Figures 6-13. The general size and shape of individual particle could be observed. Particles of durian rind extract D_1 and D_2 possessed fiber-like shape and are the same as Ac-di-Sol(R), Kollidon CL(R) and Nymcel(R). In contrast, corn starch, Explotab(R) and Starch 1500(R) possessed an ovoidal-like shape.

Particle size distributions of various disintegrants used in this study were analysed by Malvern Particle Sizer. Histograms for the particle size distributions and its cumulative percent undersize are shown in Figures 14-21, respectively. The data for average particle size and specific surface area of these disintegrants are also summarized in Table 5. The results indicated that particles of D_2 are larger than D_1.

The average particle size(dvs) decreases in the following order : D_2 > D_1 > Kollidon CL(R) > Nymcel(R) > Starch 1500(R) > Explotab(R) > Ac-di-Sol(R) > corn starch. Specific surface area, on the other hand, showed the reverse in order from the data given above.

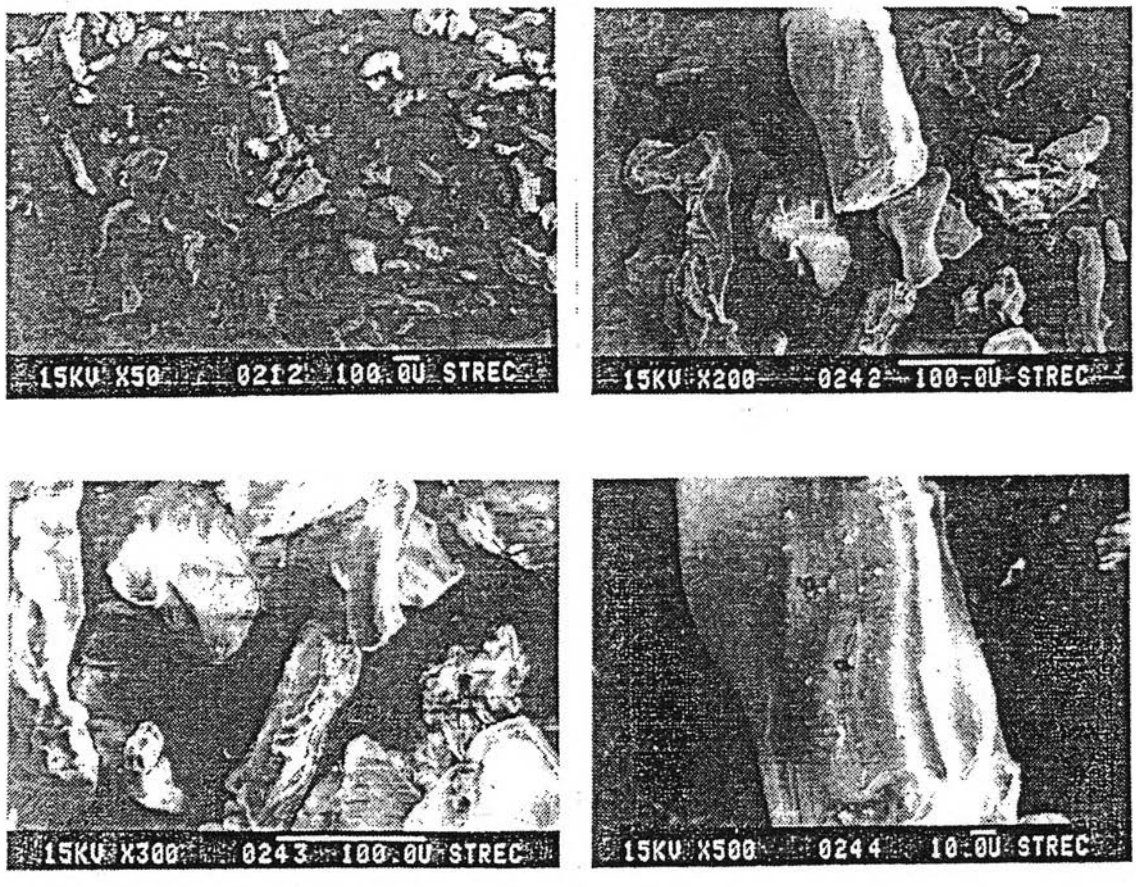


FIGURE 6 PHOTOMICROGRAPHS OF DURIAN RIND EXTRACT D_1

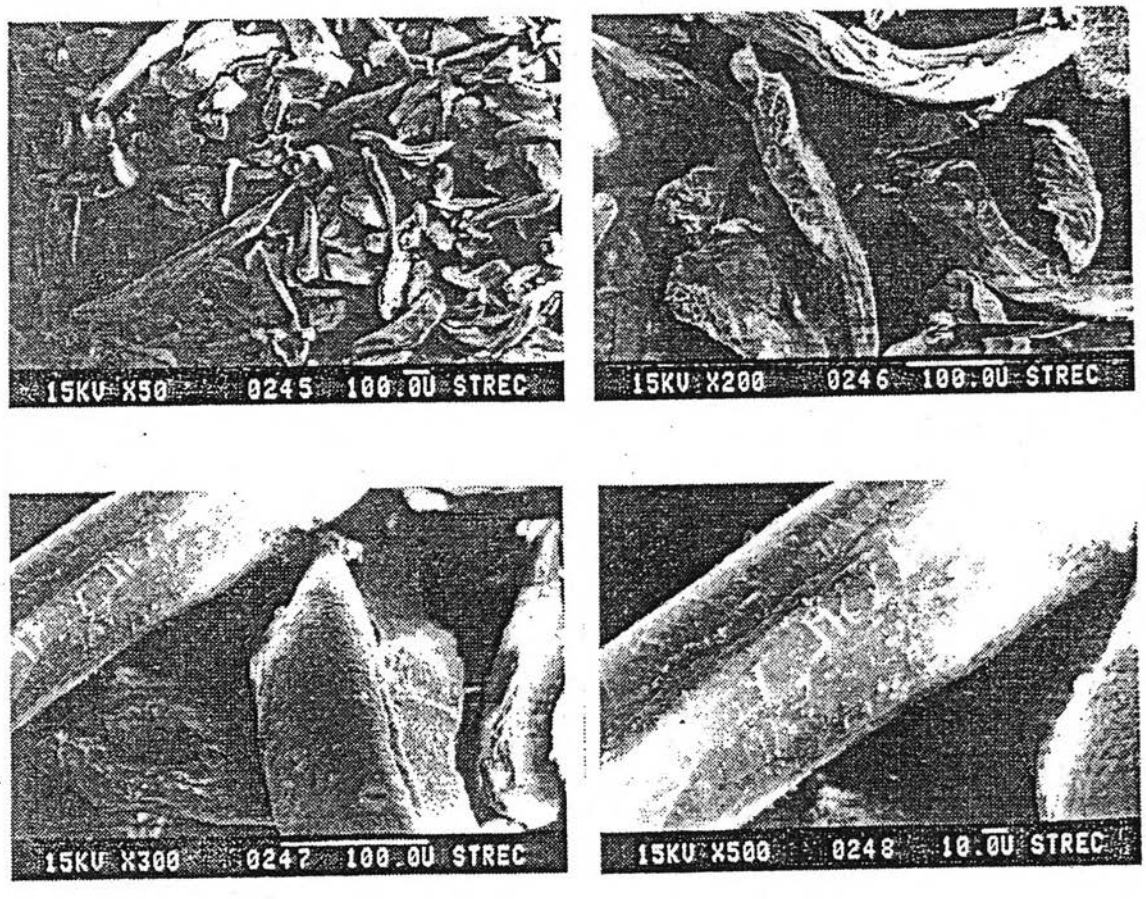


FIGURE 7. PHOTOMICROGRAPHS OF DURIAN RIND EXTRACT D_2

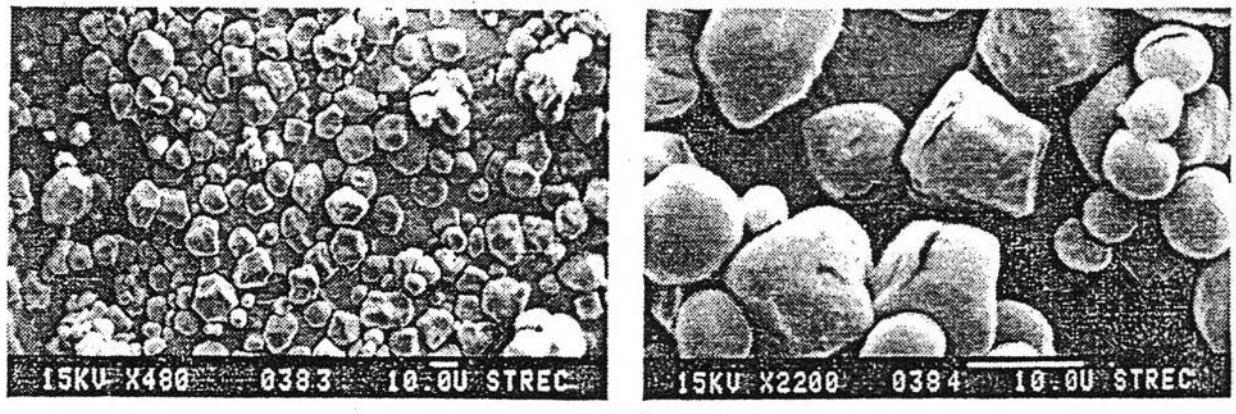


FIGURE 8 PHOTOMICROGRAPHS OF CORN STARCH

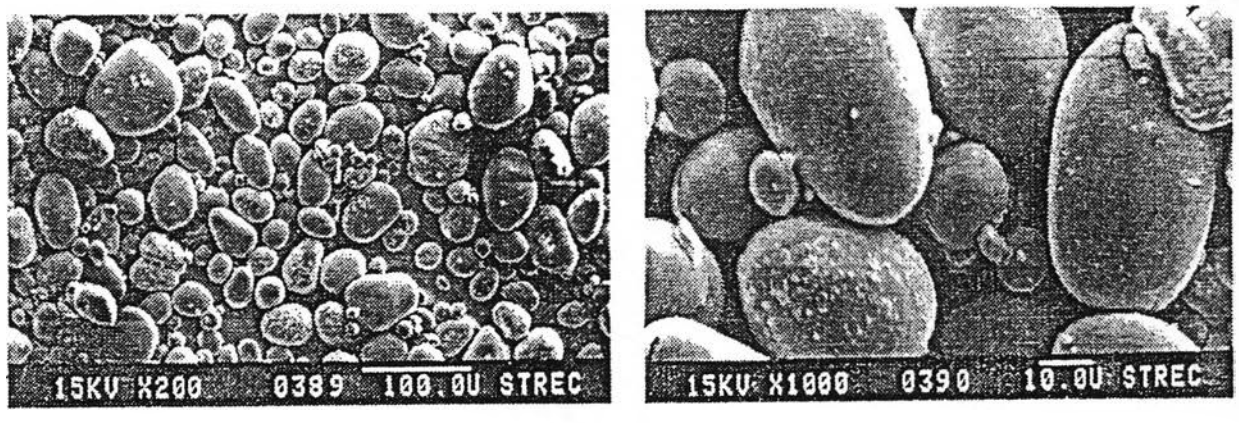


FIGURE 9 PHOTOMICROGRAPHS OF EXPLOTAB(R)

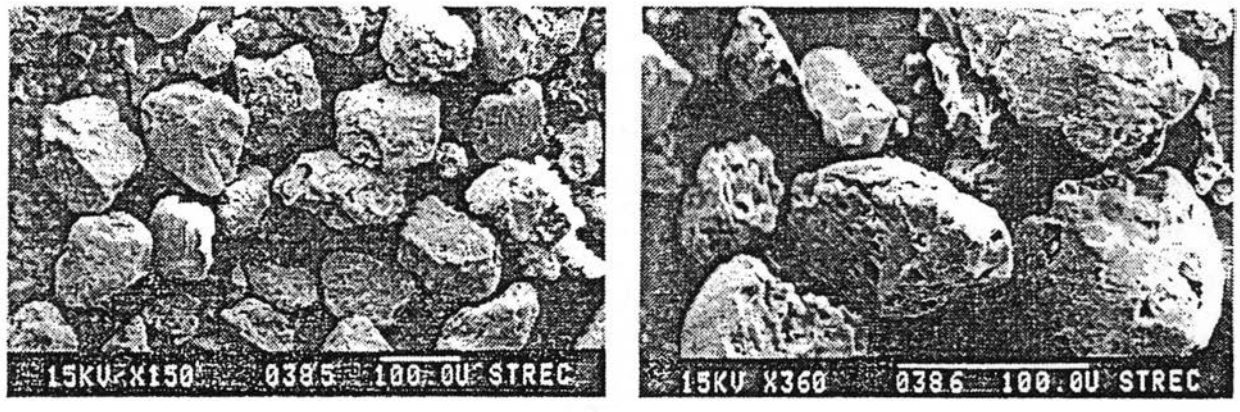


FIGURE 10 PHOTOMICROGRAPHS OF STARCH 1500 (R)

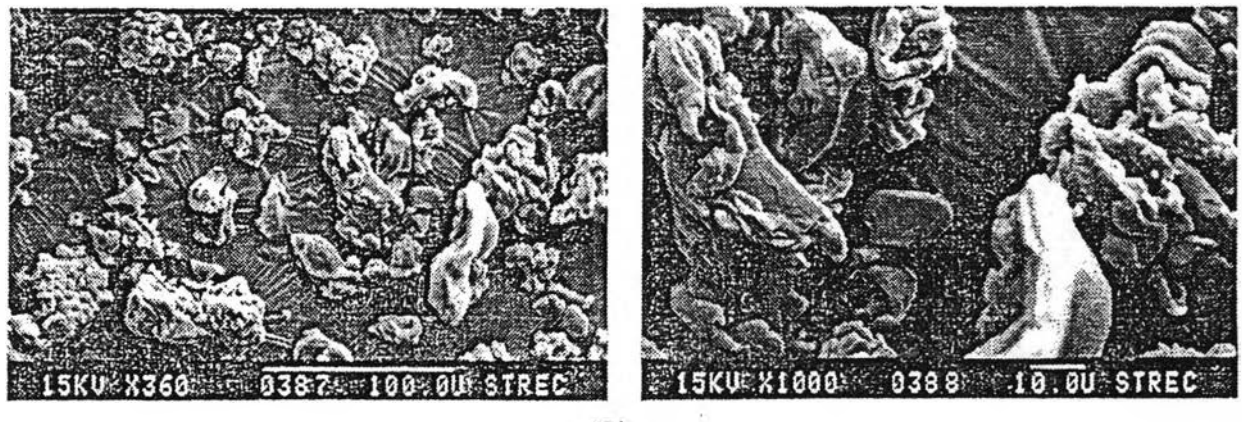


FIGURE 11 PHOTOMICROGRAPHS OF KOLLIDON CL (R)

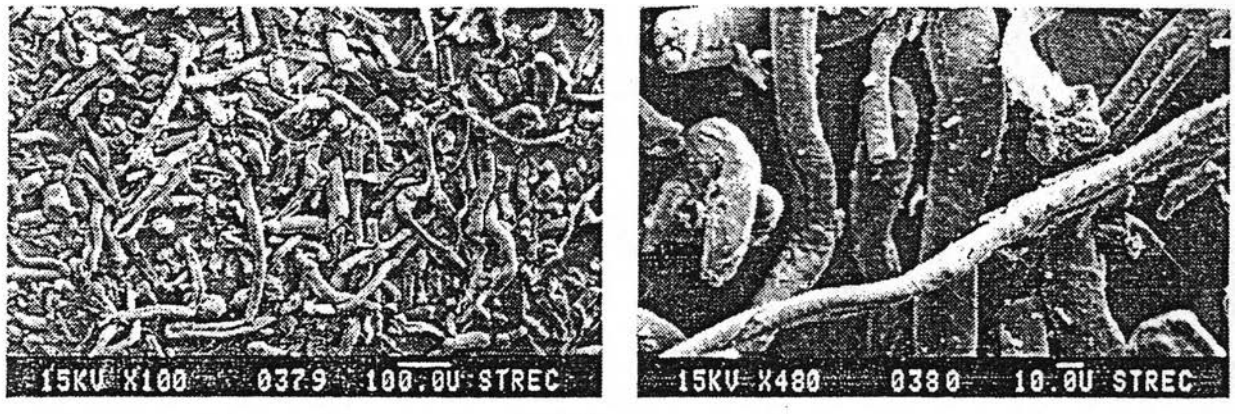


FIGURE 12 PHOTOMICROGRAPHS OF AC—DI—SOL(R)

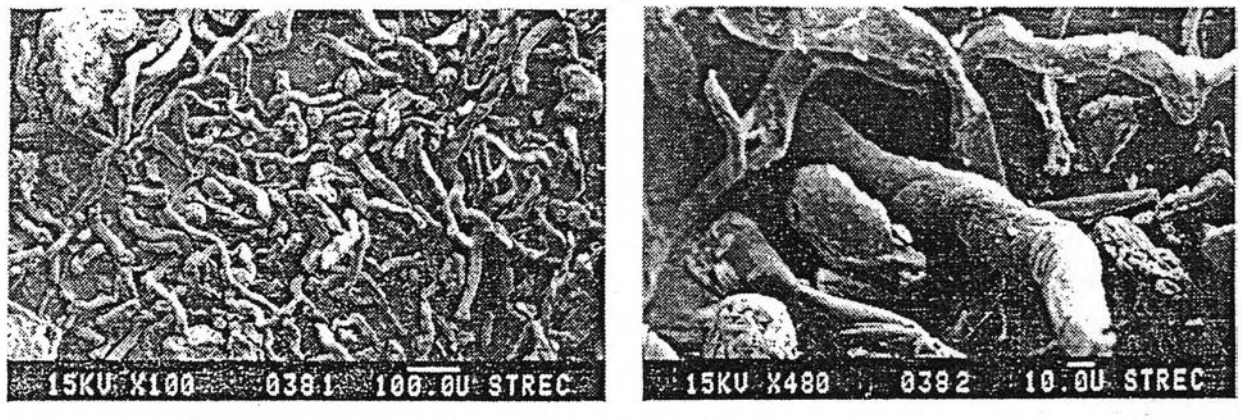
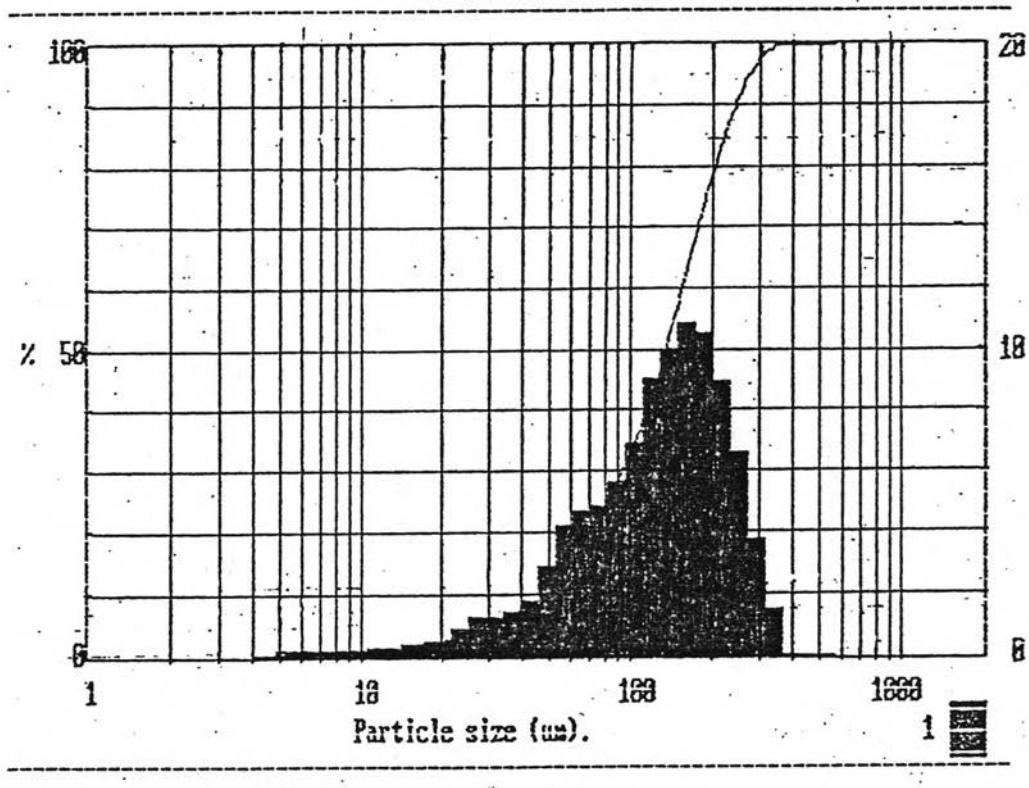
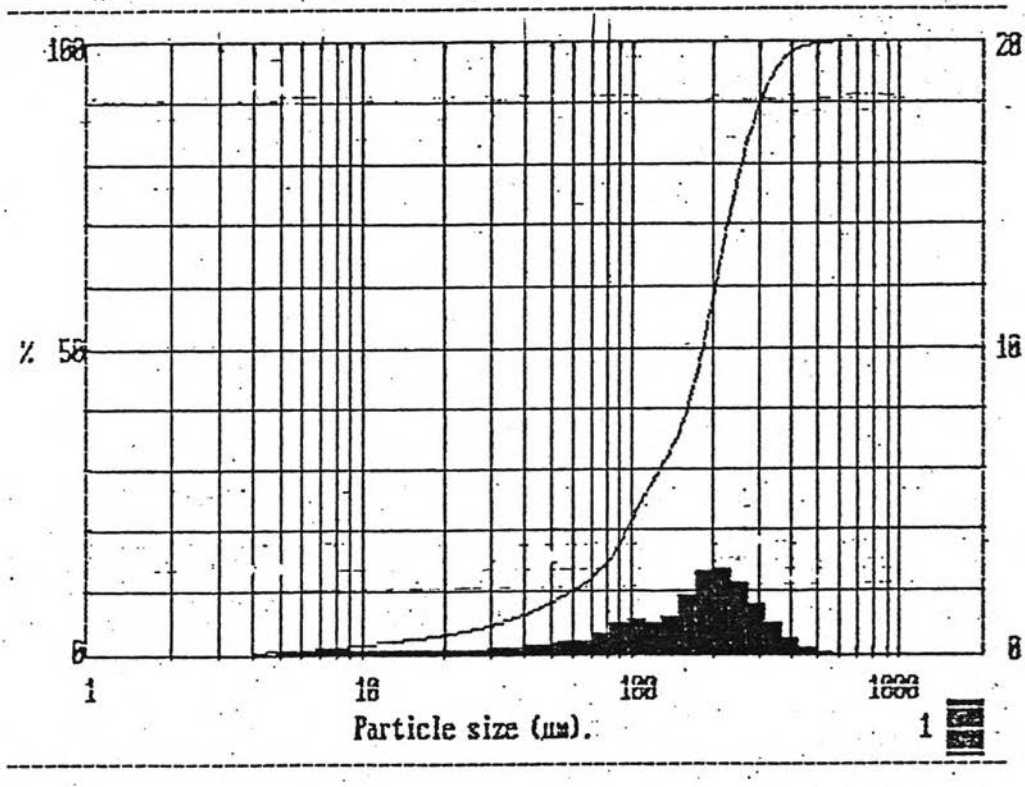


FIGURE 13 PHOTOMICROGRAPHS OF NYMCEL(R)



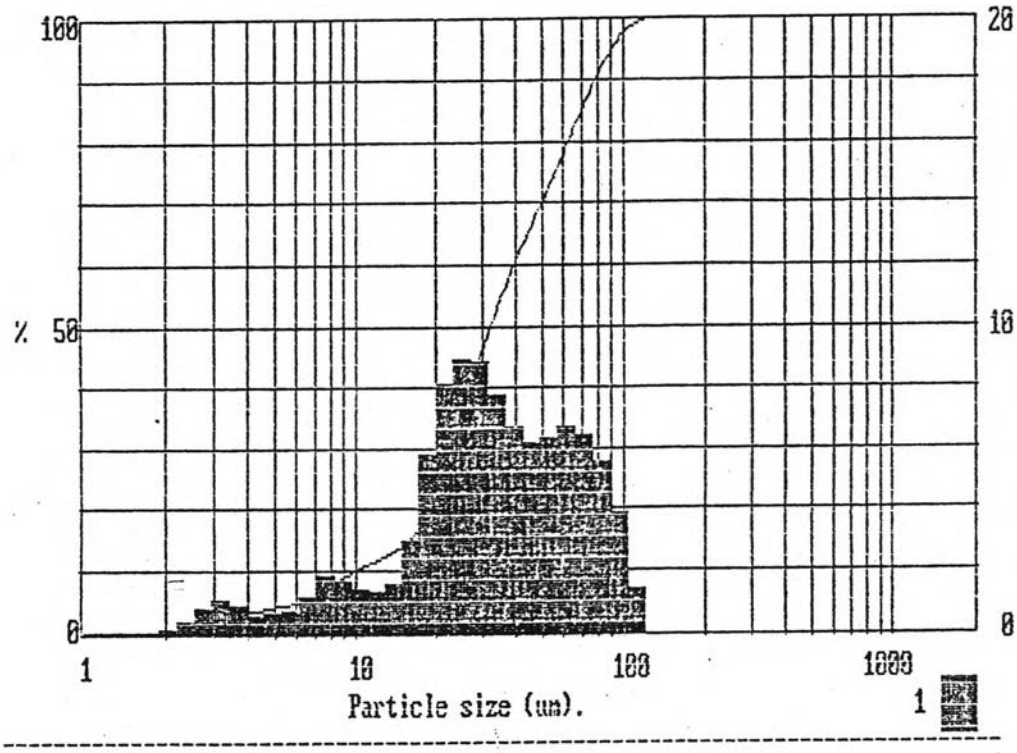
Size : microns	: under	% : in band	Size : microns	: under	% : in band	Result source= Record No. =
						Focal length = 300 mm.
564.0	100.0	0.0	53.1	12.1	2.9	Experiment type pia
487.0	100.0	0.0	45.8	9.2	1.7	Volume distribution
420.0	100.0	0.0	39.5	7.5	1.4	Beam length = 10.0 mm.
362.0	100.0	1.5	34.1	6.0	1.3	Obscuration =0.1269
312.0	98.5	3.8	29.4	4.8	1.2	Volume Conc. = 0.0372 %
270.0	94.6	6.6	25.4	3.6	0.9	Log. Diff. =3.40
233.0	88.0	9.0	21.9	2.7	0.5	Model indp
201.0	79.0	10.5	18.9	2.2	0.3	
173.0	68.5	10.9	16.3	1.9	0.3	D(v,0.5) = 133.8 um
149.0	57.6	10.0	14.1	1.6	0.3	D(v,0.9) = 242.3 um
129.0	47.6	9.1	12.1	1.2	0.2	D(v,0.1) = 48.1 um
111.0	38.5	6.9	10.5	1.0	0.2	D(4,3) = 139.4 um
95.9	31.6	5.6	9.0	0.8	0.2	D(3,2) = 97.0 um
82.7	25.9	4.9	7.8	0.6	0.2	Span = 1.5
71.4	21.0	4.7	6.7	0.5	0.2	Spec. surf. area
61.6	16.4	4.3	5.8	0.3		0.0750 sq.m./cc.

Figure 14. Histogram for the particle size distribution and cumulative percent undersize of durian rind extract, D_1



Size : microns	under	% in band	Size : microns	under	% in band	
564.0	100.0	0.1	53.1	8.9	1.5	Result source= Record No. =
487.0	99.9	0.7	45.8	7.3	1.2	Focal length = 300 mm.
420.0	99.2	2.3	39.5	6.1	0.9	Experiment type pia
362.0	96.9	4.7	34.1	5.2	0.8	Volume distribution
312.0	92.2	7.8	29.4	4.4	0.6	Beam length = 10.0 mm.
270.0	84.4	11.7	25.4	3.7	0.6	Obscuration =0.1310
233.0	72.8	13.8	21.9	3.2	0.5	Volume Conc. = 0.0437 %
201.0	59.0	13.2	18.9	2.7	0.4	Log. Diff. =4.21
173.0	45.8	9.5	16.3	2.3	0.3	Model indp
149.0	36.4	5.6	14.1	2.0	0.3	D(v,0.5) = 182.0 um
129.0	30.8	4.9	12.1	1.6	0.3	D(v,0.9) = 297.3 um
111.0	25.9	5.5	10.5	1.4	0.3	D(v,0.1) = 58.9 um
95.9	20.4	4.9	9.0	1.1	0.2	D(4,3) = 178.9 um
82.7	15.5	3.0	7.8	0.9	0.2	D(3,2) = 120.5 um
71.4	12.5	1.9	6.7	0.7	0.2	Span = 1.3
61.6	10.5	1.7	5.8	0.5		Spec. surf. area 0.0671 sq.m./cc.

Figure 15. Histogram for the particle size distribution and cumulative percent undersize of durian rind extract, D_z

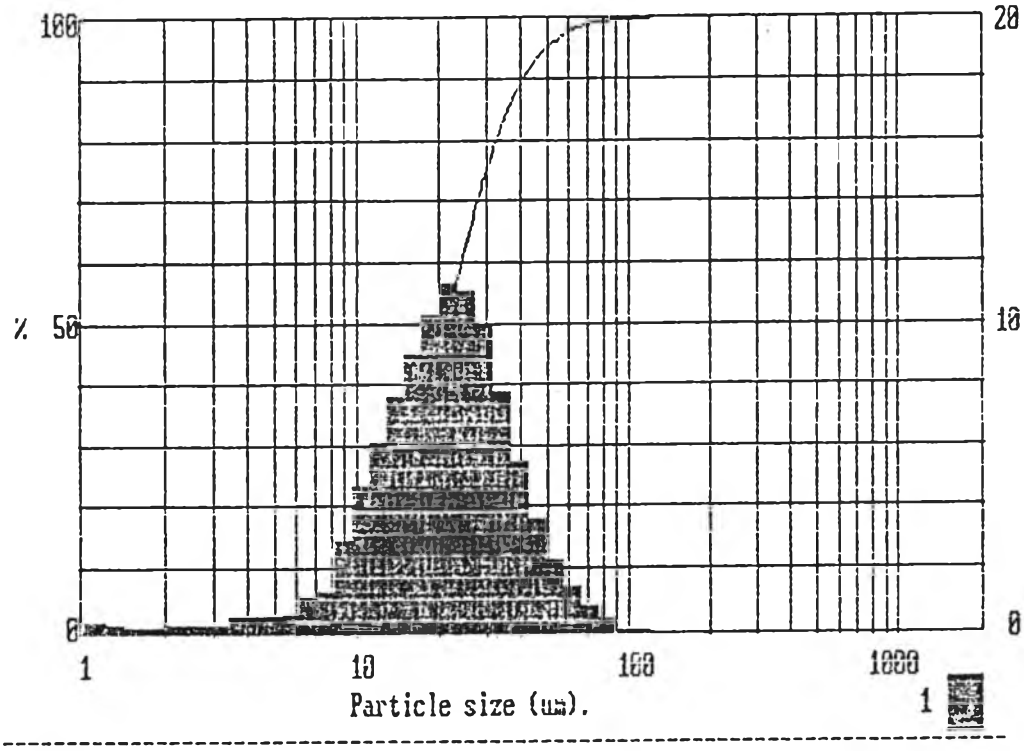


Size microns	under	% in band	Size microns	under	% in band
118.4	100.0	1.5	11.1	11.1	1.4
102.1	98.5	3.9	9.6	9.8	1.7
88.1	94.7	5.6	8.3	8.0	1.8
76.0	89.1	6.5	7.2	6.2	1.1
65.6	82.6	6.7	6.2	5.1	0.7
56.6	75.9	6.4	5.3	4.4	0.6
48.8	69.6	6.2	4.6	3.8	0.5
42.1	63.4	6.7	4.0	3.2	0.9
36.3	56.7	7.8	3.4	2.3	1.0
31.3	48.8	8.8	3.0	1.3	0.8
27.0	40.0	9.0	2.6	0.5	0.4
23.3	31.0	8.2	2.2	0.1	0.1
20.1	22.9	5.8	1.9	0.1	0.0
17.4	17.1	3.1	1.6	0.0	0.0
15.0	14.0	1.6	1.4	0.0	0.0
12.9	12.4	1.3	1.2	0.0	

Result source=
Record No. =
Focal length = 63 mm.
Experiment type oil
Volume distribution
Beam length = 2.2 mm.
Obscuration =0.1598
Volume Conc. = 0.0546 %
Log. Diff. =3.10
Model indp

D(v,0.5) = 32.0 um
D(v,0.9) = 77.7 um
D(v,0.1) = 9.9 um
D(4,3) = 38.5 um
D(3,2) = 23.1 um
Span = 2.1
Spec. surf. area
0.2944 sq.m./cc.

Figure 16. Histogram for the particle size distribution and cumulative percent undersize of Ac-di-Sol(R)

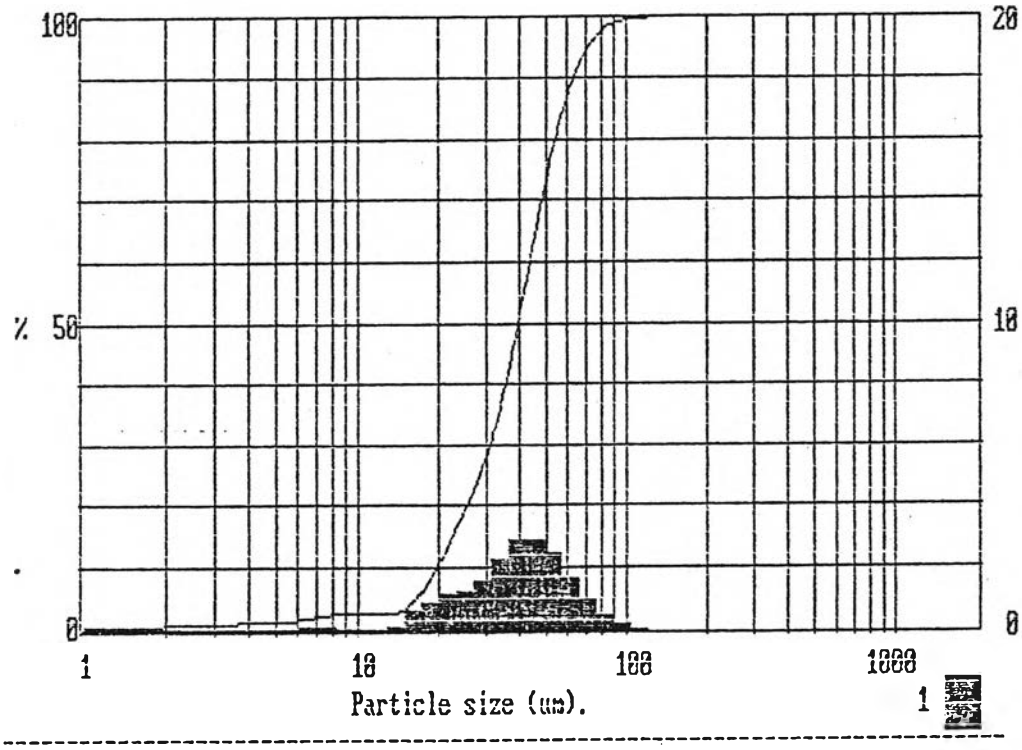


Size microns	under	% in band	Size microns	under	% in band
118.4	100.0	0.0	11.1	12.7	4.7
102.1	100.0	0.0	9.6	8.1	2.9
88.1	100.0	0.3	8.3	5.1	1.2
76.0	99.6	0.8	7.2	3.9	1.0
65.6	98.8	1.4	6.2	2.8	0.5
56.6	97.4	2.3	5.3	2.3	0.4
48.8	95.1	3.6	4.6	1.9	0.5
42.1	91.4	5.5	4.0	1.4	0.4
36.3	86.0	7.8	3.4	1.0	0.1
31.3	78.1	9.9	3.0	0.9	0.1
27.0	68.2	11.1	2.6	0.8	0.1
23.3	57.2	11.4	2.2	0.8	0.1
20.1	45.8	10.3	1.9	0.6	0.0
17.4	35.5	9.0	1.6	0.6	0.1
15.0	26.5	7.6	1.4	0.5	0.2
12.9	18.9	6.1	1.2	0.3	

Result source=
Record No. =
Focal length = 63 mm.
Experiment type pil
Volume distribution
Beam length = 2.2 mm.
Obscuration =0.1567
Volume Conc. = 0.0416 %
Log. Diff. =3.10
Model indp

D(v,0.5) = 21.2 um
D(v,0.9) = 40.3 um
D(v,0.1) = 10.3 um
D(4,3) = 23.2 um
D(3,2) = 18.3 um
Span = 1.4
Spec. surf. area
0.3826 sq.m./cc.

Figure 17. Histogram for the particle size distribution and cumulative percent undersize of corn starch

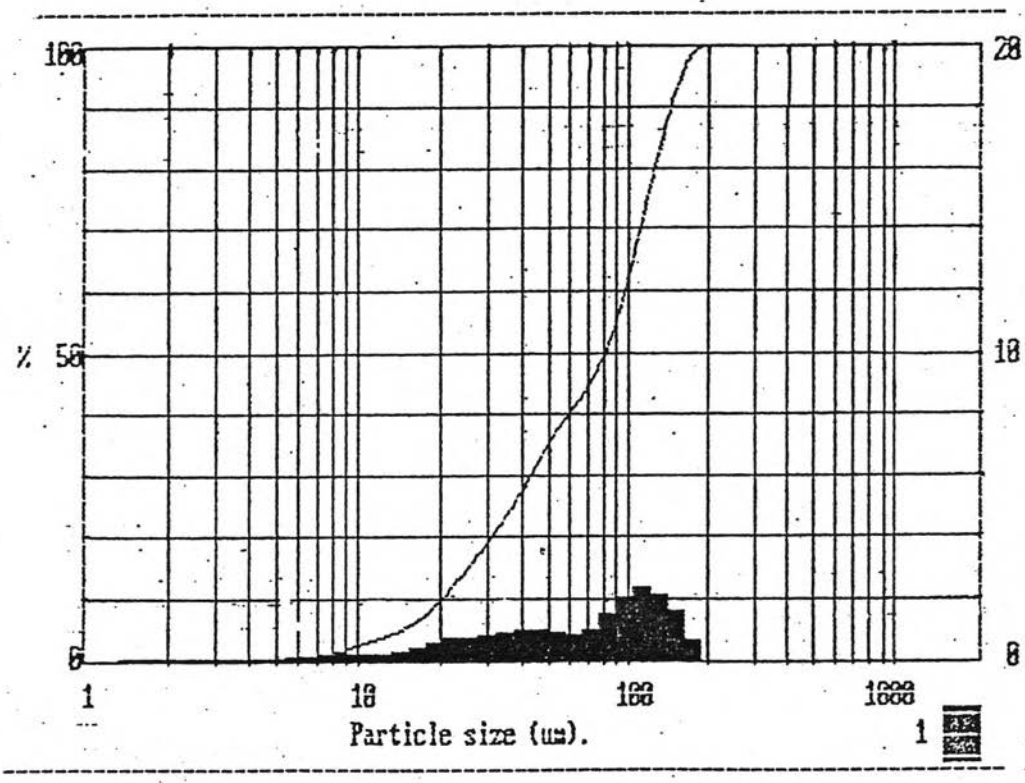


Size microns	under	% in band	Size microns	under	% in band
118.4	100.0	0.0	11.1	2.6	0.0
102.1	100.0	0.7	9.6	2.6	0.0
88.1	99.3	2.3	8.3	2.5	0.4
76.0	97.0	4.8	7.2	2.1	0.5
65.6	92.2	8.2	6.2	1.6	0.2
56.6	84.0	12.3	5.3	1.4	0.1
48.8	71.7	14.7	4.6	1.3	0.1
42.1	57.0	14.4	4.0	1.2	0.2
36.3	42.6	11.5	3.4	1.0	0.1
31.3	31.1	8.1	3.0	0.9	0.1
27.0	23.0	6.3	2.6	0.8	0.1
23.3	16.7	5.8	2.2	0.7	0.2
20.1	10.8	4.6	1.9	0.6	0.0
17.4	6.2	2.9	1.6	0.6	0.1
15.0	3.3	0.6	1.4	0.5	0.1
12.9	2.7	0.1	1.2	0.3	

Result source=
Record No. =
Focal length = 63 mm.
Experisent type pil
Volume distribution
Beam length = 2.2 mm.
Obscuration =0.1651
Volume Conc. = 0.0740 %
Log. Diff. =4.80
Model indp

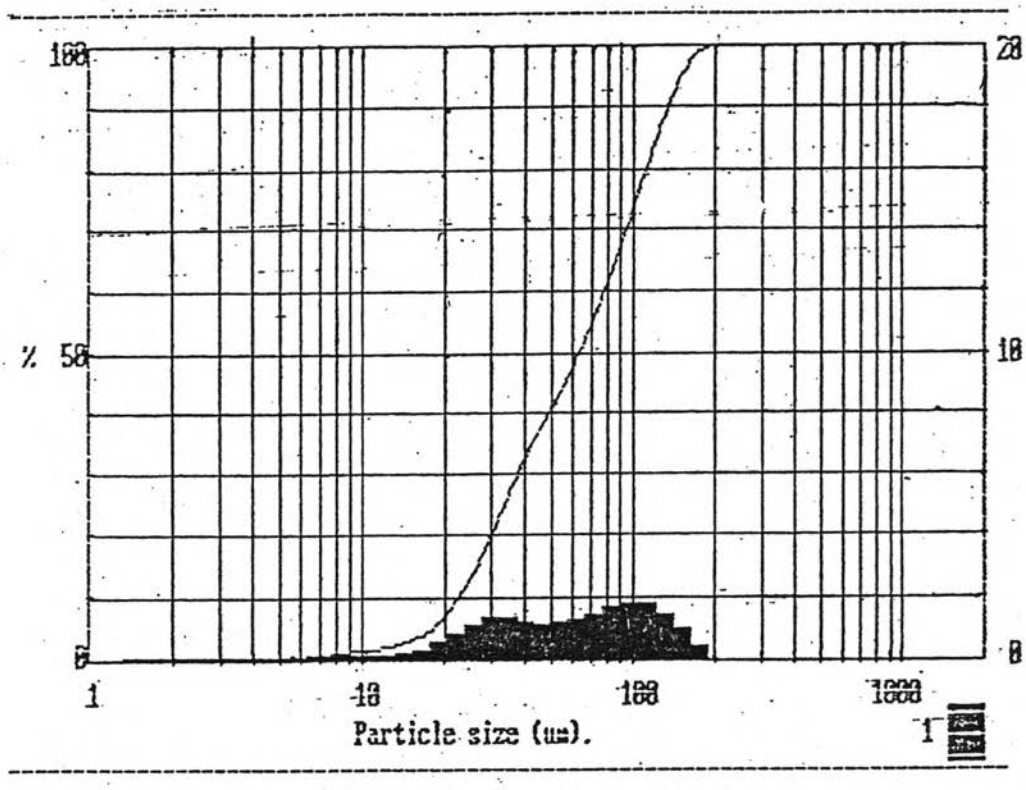
D(v,0.5) = 39.3 um
D(v,0.9) = 62.5 um
D(v,0.1) = 19.6 um
D(4,3) = 39.3 um
D(3,2) = 33.2 um
Span = 1.1
Spec. surf. area
0.2317 sq.m./cc.

Figure 18. Histogram for the particle size distribution and cumulative percent undersize of Explotab(R).



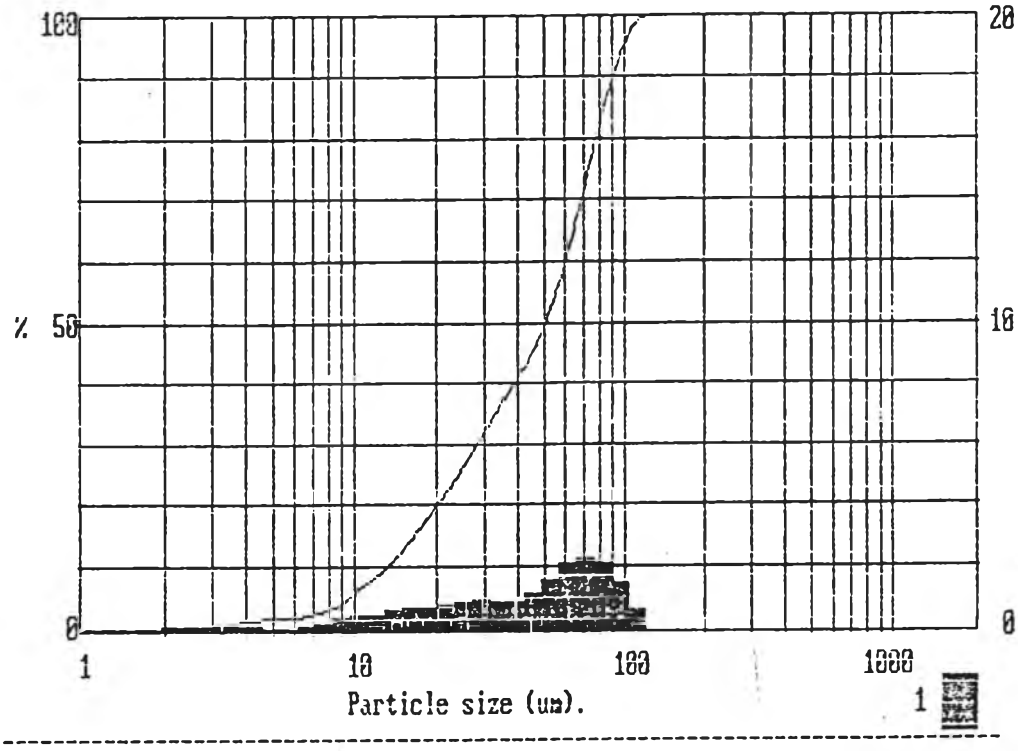
Size : microns	: under	% : in band	Size : microns	: under	% : in band	Result source= Record No. =
						Focal length = 100 mm.
188.0	100.0	3.2	17.7	7.4	2.0	Experiment type pia
162.0	96.8	8.0	15.3	5.4	1.2	Volume distribution
140.0	88.9	10.7	13.2	4.2	1.0	Beam length = 10.0 mm.
121.0	78.1	12.0	11.4	3.1	1.0	Obscuration =0.1034
104.0	66.1	10.3	9.8	2.1	0.8	Volume Conc. = 0.0166 %
89.9	55.8	7.5	8.5	1.3	0.6	Log. Diff. =5.27
77.5	48.3	5.0	7.3	0.7	0.4	Model indp
66.9	43.3	3.9	6.3	0.3	0.2	
57.7	39.4	4.2	5.4	0.1	0.1	D(v,0.5) = 80.7 um
49.8	35.2	5.0	4.7	0.0	0.0	D(v,0.9) = 142.5 um
42.9	30.2	4.8	4.1	0.0	0.0	D(v,0.1) = 20.3 um
37.1	25.4	4.4	3.5	0.0	0.0	D(4,3) = 78.9 um
32.0	21.0	3.9	3.0	0.0	0.0	D(3,2) = 48.4 um
27.6	17.1	3.6	2.6	0.0	0.0	Span = 1.5
23.8	13.5	3.3	2.2	0.0	0.0	Spec. surf. area
20.5	10.2	2.8	1.9	0.0		0.1344 sq.m./cc.

Figure 19. Histogram for the particle size distribution and cumulative percent undersize of Kollidon CL(R)



Size : microns	% under	% in band	Size : microns	% under	% in band	Result source= Record No. =
						Focal length = 100 mm.
188.0	100.0	2.0	17.7	4.3	1.3	Experiment type pia
162.0	98.0	5.1	15.3	3.1	1.1	Volume distribution
140.0	93.0	7.3	13.2	2.0	0.5	Beam length = 10.0 mm.
121.0	85.7	8.8	11.4	1.5	0.2	Obscuration =0.0982
104.0	76.9	8.7	9.8	1.2	0.3	Volume Conc. = 0.0156 %
89.9	68.2	8.2	8.5	0.9	0.4	Log. Diff. =4.64
77.5	60.0	7.2	7.3	0.5	0.3	Model_indp
66.9	52.8	6.4	6.3	0.2	0.0	
57.7	46.4	5.6	5.4	0.2	0.2	D(v,0.5) = 62.9 um
49.8	40.8	5.3	4.7	0.0	0.0	D(v,0.9) = 131.4 um
42.9	35.5	5.7	4.1	0.0	0.0	D(v,0.1) = 22.7 um
37.1	29.9	6.7	3.5	0.0	0.0	D(4,3) = 69.2 um
32.0	23.2	6.5	3.0	0.0	0.0	D(3,2) = 47.3 um
27.6	16.7	5.3	2.6	0.0	0.0	Span = 1.7
23.8	11.4	4.2	2.2	0.0	0.0	Spec. surf. area
20.5	7.2	2.9	1.9	0.0		0.1356 sq.m./cc.

Figure 20. Histogram for the particle size distribution and cumulative percent undersize of Nymcel(R)



Size : microns	under	% in band	Size : microns	under	% in band	
118.4	100.0	3.0	11.1	7.4	2.3	Result source= Record No. =
102.1	97.0	7.7	9.6	5.1	1.9	Focal length = 63 mm.
88.1	89.3	10.6	8.3	3.3	0.8	Experiment type pil
76.0	78.7	11.5	7.2	2.5	0.6	Volume distribution
65.6	67.2	10.6	6.2	1.9	0.2	Beam length = 2.2 mm.
56.6	56.6	8.1	5.3	1.7	0.2	Obscuration =0.1769
48.8	48.5	5.7	4.6	1.6	0.3	Volume Conc. = 0.0810 %
42.1	42.8	4.6	4.0	1.2	0.3	Log. Diff. =3.69
36.3	38.2	4.6	3.4	0.9	0.3	Model indp
31.3	33.6	4.8	3.0	0.6	0.2	
27.0	28.7	4.6	2.6	0.4	0.0	D(v,0.5) = 50.4 um
23.3	24.1	4.0	2.2	0.4	0.2	D(v,0.9) = 89.1 um
20.1	20.1	3.7	1.9	0.2	0.0	D(v,0.1) = 13.2 um
17.4	16.4	3.7	1.6	0.2	0.1	D(4,3) = 49.7 um
15.0	12.7	3.0	1.4	0.1	0.0	D(3,2) = 31.3 um
12.9	9.7	2.2	1.2	0.1		Span = 1.5
						Spec. surf. area 0.2241 sq.m./cc.

Figure 21. Histogram for the particle size distribution and cumulative percent undersize of Starch 1500(*)

Table 5

The Comparison of Average Particle Size and Specific Surface Area Between D_1, D_2 and Other Disintegrants.

Disintegrant	average particle size (um)		specific surface area (m^2/cc.)
	d_{vm}(1)	d_{wm}(2)	
D_1	97.0	138.4	0.0750
D_2	120.5	178.9	0.0671
Ac-di-Sol(R)	23.1	38.5	0.2944
Corn Starch	18.3	23.2	0.3826
Explotab(R)	33.2	39.2	0.2317
Kollidon CL(R)	48.4	78.9	0.1344
Nymcel(R)	47.3	69.2	0.1356
Starch 1500(R)	31.3	49.7	0.2241

(1) = volume surface mean diameter (nd^3 / nd^2)

(2) = weight moment mean diameter (nd^4 / nd^3)

(b) Bulk density, Tapped density, percent compressibility and Flow rate

The results of bulk density, tapped density, percent compressibility and flow rate are presented in Table 6. The bulk density decreased in the following order : D_1 > Explotab$^{(R)}$ > D_2 > Starch 1500$^{(R)}$ > corn starch > Ac-di-Sol$^{(R)}$ ≃ Nymcel$^{(R)}$ > Kollidon CL$^{(R)}$. For tapped density, the orders were the same as bulk density, except for Ac-di-Sol$^{(R)}$ and Nymcel$^{(R)}$, the latter appeared to be less. In addition, percent compressibilities were ranked as follows : Ac-di-Sol$^{(R)}$ > Nymcel$^{(R)}$ > corn starch > Kollidon CL$^{(R)}$ > Starch 1500$^{(R)}$ > Explotap$^{(R)}$ > D_2 > D_1. It was noticed that D_1 and D_2, which possessed lower percent compressibility are significantly superior flow rate than other disintegrants.

(c) Moisture Content

Moisture Content of different disintegrants were calculated as percent loss on drying and given in Table 7. They could be ranked as follows : Explotap$^{(R)}$ > corn starch > D_2 > Starch 1500$^{(R)}$ > Kollidon CL$^{(R)}$ > D_1 > Nymcel$^{(R)}$ > Ac-di-Sol$^{(R)}$.

(d) Hydration capacity

The results of hydration capacity of various disintegrants are presented in Table 8. The magnitude of difference on hydration capacity among various disintegrants was quite significant. They were ranked as follows : Nymcel$^{(R)}$ > D_1 > Ac-di-Sol$^{(R)}$ > D_2 > Starch 1500$^{(R)}$ ≃ Kollidon CL$^{(R)}$ > corn starch. Since Explotab$^{(R)}$ could dissolved in this experiment, it's hydration capacity could not be determined.

(e) Swelling Index

Swelling index values of various disintegrants in water and in 0.1 N hydrochloric acid are compared and given in

Table 6

Bulk Density, Tapped Density, Percent Compressibility and Flow Rate of Various Disintegrants

Disintegrant	Bulk Density[1] (gm/cm^3)	Tapped Density[1] (gm/cm^3)	Compressibility (%)	Flow rate[1] (g/sec)
D_1	0.772	1.000	22.80	9.8
D_2	0.714	0.933	23.47	11.6
Ac-di-Sol®	0.412	0.699	41.06	poor[2]
Corn Starch	0.490	0.758	35.36	poor[2]
Explotab®	0.734	0.967	24.10	poor[2]
Kollidon CL®	0.362	0.515	29.71	poor[2]
Nymcel®	0.417	0.614	36.51	poor[2]
Starch 1500®	0.625	0.862	27.49	poor[2]

(1) = average of two determinations

(2) = powder could not flow through the orifice of the apparatus

Table 7

Moisture Content of Various Disintegrants

Disintegrant	% Loss on drying(1)
D_1	9.01
D_2	11.02
Ac-di-Sol®	6.40
Corn Starch	13.85
Explotab®	14.95
Kollidon CL®	9.30
Nymcel®	7.95
Starch 1500®	10.35

(1) = average of two determinations

Table 8

Hydration Capacity of Durian Rind Extract Compared with Other Disintegrants.

Disintegrant	Hydration Capacity (cm^3/gm)(1)
D_1	7.95 (partially dissolved)
D_2	5.00 (partially dissolved)
Ac-di-Sol(R)	6.60
Corn Starch	1.98
Explotab(R)	dissolved
Kollidon CL(R)	4.23
Nymcel(R)	18.45
Starch 1500(R)	4.26

(1) = average of two determinations

Table 9. The group of particle which are ovoidal in shape such as corn starch, Explotab$^{(R)}$ and Starch 1500$^{(R)}$, others are fiber-like shape. Significant differences ($P > 0.05$) on swelling between two solvents could be observed in Ac-di-Sol$^{(R)}$, Explotab$^{(R)}$ and Nymcel$^{(R)}$. The results obtained shown that swelling ability in water decrease in the following order : Explotab$^{(R)}$ > Nymcel$^{(R)}$ > D_1 > Ac-di-Sol$^{(R)}$ > Kollidon CL$^{(R)}$ > corn starch $\simeq$ Starch 1500$^{(R)}$. In the case of swelling in 0.1 N hydrochloric acid, the order of decrease are : D_1 > Nymcel$^{(R)}$ > Ac-di-Sol$^{(R)}$ > Kollidon CL$^{(R)}$ > Explotab$^{(R)}$ $\simeq$ Starch 1500$^{(R)}$ > corn starch. Although D_2 could swell readily in both water and in 0.1 N hydrochloric acid, the swelling index could not be determined since some particles dissolved immediately. The relationship between swelling index and hydration capacity of various disintegrants are shown in Figure 22. It may be seen that, the disintegrants which possessed higher swelling index tended to have higher value of hydration capacity.

TABLET EVALUATION

Tablets prepared by direct compression using α-lactose monohydrate or dibasic calcium phosphate dihydrate as diluent and D_1, D_2, Ac-di-Sol$^{(R)}$, corn starch, Explotab$^{(R)}$, Kollidon CL$^{(R)}$, Nymcel$^{(R)}$ or Starch 1500$^{(R)}$ as disintegrant, compressed at three compressional forces were observed for their physical properties as follows : (a) weight variation (b) thickness (c) hardness (d) friability (e) disintegration time (f) water uptake. Data from these measurements are shown in Tables 10-25.

(a) Weight variation of tablets

The average weight and standard deviation of tablets for each formulation are shown in Tables 10-25. In all cases, weight variation were well within the limit of USP standard.

Table 8

Swelling Index[1] of Durian Rind Extract in Water and in 0.1 N HCl Compared with Other Disintegrants

Disintegrant	swelling solvent		t test	F value
	water	0.1 N HCl		
D_1	3.04	2.47	NS	0.88
D_2	....[2]	....[2]	....	....
Ac-di-Sol®	2.50	1.92	S	63.47
Corn Starch®	1.31	1.31	NS	0.29
Explotab®	3.64	1.45	S	18.80
Kollidon CL®	1.65	1.61	NS	1.75
Nymcel®	3.34	2.10	S	87.45
Starch 1500®	1.32	1.44	NS	1.08

(1) average of two determinations.

(2) Some particles dissolve immediately and swelling index could not be determined

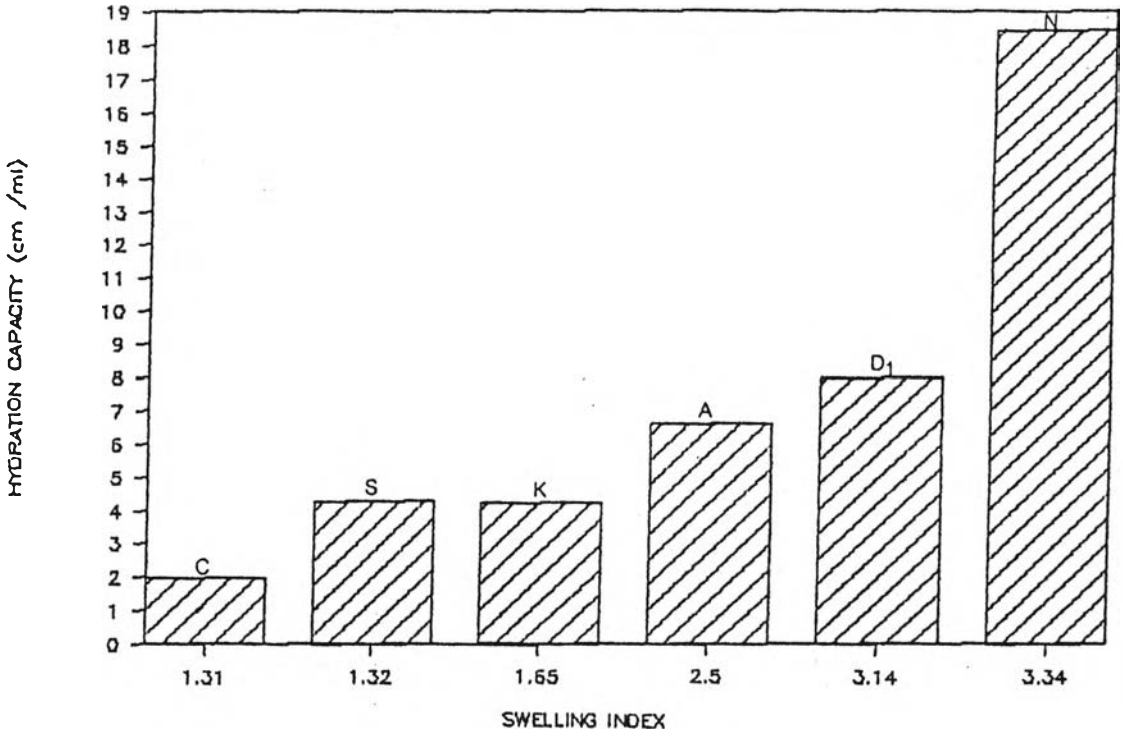


Figure 22. The relationship between swelling index and hydration capacity of various disintegrants : C = corn starch, S = Starch 1500, K = Kollidon CL, A = Ac-di-Sol, D_1 = D_1 and N = Nymcel

Table 10

Physical Properties of Dibasic Calcium Phosphate Dihydrate Tablets Containing Various Concentrations of D_1 at Different Compression Pressures.

Compression pressure (kg) / Physical properties of tablets		Concentration (%)				
		0	0.5	1	2	5
500	WEIGHT (mg±S.D.)	249.2±0.7	252.9±0.8	252.7±0.7	255.2±0.5	254.1±0.9
	THICKNESS (mm±S.D)	2.541±0.003	2.558±0.005	2.586±0.004	2.615±0.003	2.662±0.017
	HARDNESS (Kp±S.D.)	2.81±0.61	3.21±0.30	2.26±0.54	2.62±0.42	2.01±0.85
	FRIABILITY (%)	1.59	1.40	1.47	1.38	1.78
	DISINTEGRATION TIME (SEC)	>30 min	875.83	94.67	36	24.67
	RANGE		(510-1690)	(48-170)	(35-37)	(24-25)
	APPLIED PRESSURE (kg)	506.8	506.8	463.4	506.8	458.6
	RANGE	482-531	482-531	434-492	482-531	434-482
1000	WEIGHT (mg±S.D.)	247.2±1.0	254.3±0.7	253.1±0.7	256.4±1.1	255.8±0.6
	THICKNESS (mm±S.D)	2.386±0.009	2.466±0.005	2.463±0.008	2.513±0.004	2.533±0.004
	HARDNESS (Kp±S.D.)	6.85±0.84	5.58±0.35	5.03±0.28	4.96±0.33	4.55±0.32
	FRIABILITY (%)	0.82	0.62	0.77	0.74	0.75
	DISINTEGRATION TIME (SEC)	>30 min	>30 min	153.33	55	38
	RANGE			(100-250)	(48-65)	(36-41)
	APPLIED PRESSURE (kg)	1018.5	989.5	989.5	965.4	977.56
	RANGE	989-1047	965-1013	965-1013	941-989	965-989
1500	WEIGHT (mg±S.D.)	249.4±0.4	251.9±1.2	254.5±0.9	252.4±1.3	254.2±2.0
	THICKNESS (mm±S.D)	2.344±0.008	2.359±0.011	2.394±0.012	2.382±0.008	2.438±0.029
	HARDNESS (Kp±S.D.)	10.96±0.67	9.97±0.57	9.33±1.05	8.04±0.64	6.58±0.70
	FRIABILITY (%)	0.48	0.56	0.52	0.44	0.48
	DISINTEGRATION TIME (SEC)	>30 min	>30 min	309.67	107	56.17
	RANGE			(170-465)	(95-150)	(55-60)
	APPLIED PRESSURE (kg)	1457.8	1472.2	1424.0	1448.1	1440.8
	RANGE	1419-1496	1448-1496	1399-1496	1409-146	1399-1481

Table 11

Physical Properties of Dibasic Calcium Phosphate Dihydrate Tablets Containing Various Concentrations of D_2 at Different Compression Pressures.

Compression pressure (kg) / Physical properties of tablets	Concentration (%)				
	0	0.5	1	2	5
500 WEIGHT (mg+S.D.)	249.2±0.7	248.7±0.5	249.5±0.6	250.6±0.6	249.4±0.7
THICKNESS (mm+S.D)	2.54±0.003	2.584±0.004	2.599±0.003	2.635±0.007	2.695±0.008
HARDNESS (Kp+S.D.)	2.91±0.61	2.21±0.86	1.80±0.98	1.21±0.77	0.74±0.60
FRIABILITY (%)	1.59	2.15	2.23	2.64	3.51
DISINTEGRATION TIME (SEC)	>30 min	247.87	95.17	48	34.33
RANGE		(190-310)	(65-140)	(42-56)	(32-39)
APPLIED PRESSURE (kg)	506.8	482.7	482.7	477.9	482.7
RANGE	482-531	473-492	473-492	268-487	473-492
1000 WEIGHT (mg+S.D.)	247.2±1.0	251.6±1.8	249.3±0.5	249.1±0.4	249.7±0.5
THICKNESS (mm+S.D)	2.386±0.009	2.457±0.006	2.440±0.006	2.455±0.007	2.517±0.011
HARDNESS (Kp+S.D.)	6.85±0.84	611±0.321	5.85±0.45	5.33±0.30	4.32±0.32
FRIABILITY (%)	0.82	6.89	0.94	1.00	1.11
DISINTEGRATION TIME (SEC)	>30 min	>30 min	178.2	97.17,	49.33
RANGE			(110-300)	(85-120)	(47-52)
APPLIED PRESSURE (kg)	1018.5	989.6	970.2	965.48	955.76
RANGE	989-1047	965-1013	955-984	950-979	936-975
1500 WEIGHT (mg+S.D)	249.4±2.4	250.7±0.8	249.8±0.60	249.3±0.4	249.8±0.3
THICKNESS (mm+S.D)	2.344±0.008	2.358±0.008	2.353±0.007	2.359±0.009	2.421±0.007
HARDNESS (Kp+S.D.)	10.96±0.67	10.06±0.62	9.83±0.53	9.29±0.58	7.07±0.72
FRIABILITY (%)	0.67	0.58	0.57	0.61	0.63
DISINTEGRATION TIME (SEC)	>30 min	>30 min	502.53	138.53	73.33
RANGE			(200-960)	(100-201)	(72-75)
APPLIED PRESSURE (kg)	1457.8	1469.8	1453.0	1465.0	1460.2
RANGE	1419-1496	1438-1501	1409-1496	1433-1496	1433-1486

Table 12

Physical Properties of Dibasic Calcium Phosphate Dihydrate Tablets Containing Various Concentrations of Ac-di-Sol(R) at Different Compression Pressures.

Compression pressure (kg) / Physical properties of tablets	Concentration (%)				
	0	0.5	1	2	5
500 WEIGHT (mg+S.D.)	249.2±0.7	251.2±1.3	250.4±0.9	254.0±0.8	252.1±0.5
THICKNESS (mm+S.D)	2.541±0.003	2.584±0.007	2.591+0.003	2.638±0.003	2.682±0.004
HARDNESS (Kp+S.D.)	2.91±0.61	3.18±0.58	3.16±0.50	2.82±0.30	2.36±0.57
FRIABILITY (%)	1.59	1.73	1.68	1.71	1.81
DISINTEGRATION TIME (SEC)	>30 m	27.33	14.33	10.17	7.67
RANGE		(23-31))	(13-16)	(9-12)	(6-10)
APPLIED PRESSURE (kg)	506.8	494.8	482.7	499.6	473.0
RANGE	482-531	458-531	474-492	477-521	458-487
1000 WEIGHT (mg+S.D.)	247.2±1.0	250.6±0.5	249.9±2.2	254.4±1.5	252.8±1.0
THICKNESS (mm+S.D)	2.386±0.009	2.450±0.012	2.447±0.025	2.501±0.244	2.515±0.009
HARDNESS (Kp+S.D.)	6.85±0.84	6.47±0.92	6.97±0.42	6.51±0.51	5.66±0.73
FRIABILITY (%)	0.82	0.87	0.83	0.72	0.62
DISINTEGRATION TIME (SEC)	>30 min	72	24.33	14.67	7.67
RANGE		(58-87)	(19-33)	(13-17)	(6-10)
APPLIED PRESSURE (kg)	1018.5	958.1	946.10	994.4	975.00
RANGE	989-1047	9417-975	965-1023	946-1004	902-970
1500 WEIGHT (mg+S.D.)	249.4±0.4	250.1±0.7	250.6±0.7	251.0±0.5	249.5±0.4
THICKNESS (mm+S.D)	2.344±0.008	2.370±0.011	2.378±0.008	2.395±0.008	2.414±0.003
HARDNESS (Kp+S.D.)	10.96±0.67	9.78±1.33	10.37±0.43	9.82±1.01	9.10±0.55
FRIABILITY (%)	0.67	0.53	0.51	0.46	0.45
DISINTEGRATION TIME (SEC)	>30 min	75.83	25.33	15.383	11
RANGE		(52-100)	(23-28)	(14-17)	(10-12)
APPLIED PRESSURE (kg)	1457.8	1453.0	1440.9	1469.9	1460.2
RANGE	1419-1496	1424-1481	1388-1481	1443-1486	1424-1486

Table 13

Physical Properties of Dibasic Calcium Phosphate Dihydrate Tablets Containing Various Concentrations of Corn Starch at Different Compression Pressures.

Compression pressure (kg) \ Physical properties of tablets		Concentration (%)			
		0	0.5	1	2	5
500	WEIGHT (mg+S.D.)	249.2±0.7	255.0±0.6	253.3±0.7	253.4±0.9	258.7±0.6
	THICKNESS (mm+S.D)	2.541±0.003	2.607±0.004	2.591±0.003	2.598±0.005	2.681±0.004
	HARDNESS (Kp+S.D.)	2.91±0.61	2.58±0.91	3.19±0.38	2.81±0.73	1.90±0.88
	FRIABILITY (%)	1.59	1.57	1.58	1.53	1.80
	DISINTEGRATION TIME (SEC)	>30 min	>30 min	>30 min	1450.17	189
	RANGE				(1080-1910)	(161-240)
	APPLIED PRESSURE (kg)	506.8	475.5	475.5	482.7	487.5
	RANGE	482-531	458-492	458-492	458-506	473-502
1000	WEIGHT (mg+S.D.)	247.2±1.0	253.7±0.4	251.8±2.1	254.0±1.0	259.8±0.5
	THICKNESS (mm+S.D)	2.386±0.009	2.453±0.003	2.445±0.003	2.465±0.018	2.545±0.005
	HARDNESS (Kp+S.D.)	6.85±0.84	6.59±0.59	5.97±0.63	6.45±0.46	5.37±0.37
	FRIABILITY (%)	0.82	0.80	0.83	0.85	0.93
	DISINTEGRATION TIME (SEC)	>30 min	>30 min	>30 min	>30 min	74.5
	RANGE				(60-90)	(10-14)
	APPLIED PRESSURE (kg)	1018.5	972.6	936.4	999.2	989.5
	RANGE	989-1047	955-989	917-955	975-1023	965-1013
1500	WEIGHT (mg+S.D.)	249.4±0.4	249.1±0.7	250.8±0.6	250.2±0.5	250.6±0.3
	THICKNESS (mm+S.D)	2.344±0.008	2.348±0.011	2.381±0.009	2.365±0.009	2.402±0.011
	HARDNESS (Kp+S.D.)	10.96±0.67	9.31±1.031	10.09±1.05	9.27±1.674	9.36±0.91
	FRIABILITY (%)	0.67	0.57	0.53	0.49	0.49
	DISINTEGRATION TIME (SEC)	>30 min	>30 min	>30 min	>30 min	80.83
	RANGE					(56-107)
	APPLIED PRESSURE (kg)	1457.8	1448.1	1477.1	1455.3	1433.6
	RANGE	1419-1496	1424-1472	1453-1501	1419-1491	1404-1462

Table 14

Physical Properties of Dibasic Calcium Phosphate Dihydrate Tablets Containing Various Concentrations of Explotab(*) at Different Compression Pressures.

Compression pressure (kg) \ Physical properties of tablets	Concentration (%)				
	0	0.5	1	2	5
500 WEIGHT (mg+S.D.)	249.2±0.7	252.2±1.1	252.8±0.7	254.5±0.7	259.2±0.9
THICKNESS (mm+S.D)	2.541±0.003	2.587±0.012	2.583±0.003	2.595±0.004	2.697±0.004
HARDNESS (Kp+S.D.)	2.81±0.61	3.27±0.56	2.82±0.68	2.21±0.86	1.28±0.79
FRIABILITY (%)	1.59	1.56	1.74	1.73	2.09
DISINTEGRATION TIME (SEC)	>30 m	69.17	24.17	15.17	8
RANGE		(33-105)	(22-27)	(15-16)	(7-10)
APPLIED PRESSURE (kg)	506.8	475.5	494.8	506.8	502.0
RANGE	482-531	458-492	482-506	482-531	482-521
1000 WEIGHT (mg+S.D.)	247.2±1.0	253.6±1.1	251.5±1.2	256.6±1.4	260.7±1.1
THICKNESS (mm+S.D)	2.386±0.009	2.470±0.006	2.434±0.009	2.491±0.010	2.515±0.008
HARDNESS (Kp+S.D.)	6.85±0.84	6.24±0.50	6.62±0.48	5.32±0.31	4.75±0.30
FRIABILITY (%)	0.82	0.83	0.87	0.89	0.85
DISINTEGRATION TIME (SEC)	>30 min	63.83	48.17	17.5	11.67
RANGE		(50-80))	(30-65)	(17-18)	(10-14)
APPLIED PRESSURE (kg)	1018.5	931.6	972.6	977.5	977.5
RANGE	989-1047	907-955	941-1004	941-1013	941-1013
1500 WEIGHT (mg+S.D.)	249.4±0.4	250.6±0.7	251.4±0.7	249.7±0.8	250.0±0.7
THICKNESS (mm+S.D)	2.344±0.008	2.368±0.008	2.385±0.013	2.378±0.010	2.414±0.008
HARDNESS (Kp+S.D.)	10.96±0.67	10.24±1.01	9.74±1.433	9.63±1.634	9.03±0.88
FRIABILITY (%)	0.67	0.55	1.43	0.56	0.62
DISINTEGRATION TIME (SEC)	>30min	80.33	47.33	36	23.83
RANGE		(71-110)	(45-51)	(33-45)	(22-25)
APPLIED PRESSURE (kg)	1457.8	1472.3	1445.7	1460.2	1467.4
RANGE	1419-1496	1448-1496	1409-1481	1424-1496	1438-1496

Table 15

Physical Properties of Dibasic Calcium Phosphate Dihydrate Tablets Containing Various Concentrations of Kollidon CL(®) at Different Compression Pressures.

Compression pressure (kg) / Physical properties of tablets	Concentration (%)				
	0	0.5	1	2	5
500 WEIGHT (mg+S.D.)	249.2±0.7	253.1±1.0	250.1±0.7	252.8±1.0	252.1±0.5
THICKNES (mm+S.D)	2.541±0.003	2.600±0.018	2.579±0.004	2.643±0.005	2.733±0.004
HARDNESS (Kp+S.D.)	2.91±0.61	3.30±0.68	2.91±0.72	2.39±0.58	1.92±0.68
FRIABILITY (%)	1.59	1.63	1.45	1.65	1.44
DISINTEGRATION TIME (SEC)	>30 min	117.33	45.5	21.5	7.5
RANGE		(95-135)	(35-57)	(19-24)	(6-10)
APPLIED PRESSURE (kg)	506.8	499.6	506.8	489.9	511.7
RANGE	482-531	468-531	482-531	473-506	492-531
1000 WEIGHT (mg+S.D.)	247.2±1.0	250.3±1.5	250.8±0.9	252.6±0.5	253.3±1.2
THICKNESS (mm+S.D)	2.386±0.009	2.437±0.008	2.459±0.004	2.495±0.004	2.599±0.008
HARDNESS (Kp+S.D.)	6.85±0.84	6.48±0.39	5.89±0.44	5.44±0.34	4.61±0.45
FRIABILITY (%)	0.82	0.73	0.76	0.71	0.60
DISINTEGRATION TIME (SEC)	>30 min	322.33	40.33	22.17	7.17
RANGE		225-391)	(37-43)	(16-27)	(6-9)
APPLIED PRESSURE (kg)	1018.5	979.9	963.00	996.8	936.40
RANGE	989-1047	941-1018	950-975	975-1018	902-970
1500 WEIGHT (mg+S.D.)	249.4±0.4	249.2±1.1	250.3±0.7	250.1±0.5	249.5±0.8
THICKNESS (mm+S.D)	2.344±0.008	2.361±0.011	2.384±0.008	2.410±0.007	2.482±0.008
HARDNESS (Kp+S.D.)	10.96±67	9.72±1.186	10.06±1.11	9.20±0.574	7.24±0.82
FRIABILITY (%)	0.67	0.54	0.47	0.47	0.42
DISINTEGRATION TIME (SEC)	>30 min	259	90.67	20.83	8
RANGE		(190-312)	(72-120)	(19-23)	(7-9)
APPLIED PRESSURE (kg)	1457.8	1460.2	1474.7	1467.4	1465.0
RANGE	1419-1496	1424-1496	1448-1501	1438-1496	1438-1491

Table 16

Physical Properties of Dibasic Calcium Phosphate Dihydrate Tablets Containing Various Concentrations of Nymcel(*) at Different Compression Pressures.

Compression pressure (kg) / Physical properties of tablets	Concentration (%)				
	0	0.5	1	2	5
500 WEIGHT (mg+S.D.)	249.2±0.7	254.8±0.7	251.8±1.2	252.2±0.7	248.6±0.7
THICKNESS (mm+S.D)	2.541±0.003	2.598±0.003	2.584±0.005	2.580±0.005	2.601±0.003
HARDNESS (Kp+S.D.)	2.91±0.61	2.97±0.58	3.04±0.53	3.44±0.37	3.23±0.31
FRIABILITY (%)	1.59	1.67	1.56	1.40	1.47
DISINTEGRATION TIME (SEC)	>30 min	32.17	19	12.67	11.83
RANGE		(26-46)	(18-20)	(12-13)	(10-15)
APPLIED PRESSURE (kg)	506.8	506.8	506.8	506.8	482.7
RANGE	482-531	482-531	482-531	482-531	468-497
1000 WEIGHT (mg+S.D.)	247.2±1.1	257.0±1.8	252.9±1.0	253.1±0.6	248.4±0.5
THICKNESS (MM+S.D)	2.386±0.009	2.504±0.018	2.468±0.015	2.473±0.003	2.466±0.005
HARDNESS (Kp+S.D.)	6.85±0.84	5.93±0.51	5.79±0.59F	6.45±0.55	6.35±0.30
FRIABILITY (%)	0.82	0.90	0.80	0.72	0.73
DISINTEGRATION TIME (SEC)	>30 min	47.17	21.83	16.17	16.83
RANGE		(35-56)	(20-23)	(15-18)	(15-18)
APPLIED PRESSURE (kg)	1018.5	841.3	965.4	1037.8	950.96
RANGE	989-1047	717-965	946-984	1013-1061	917-984
1500 WEIGHT (mg+S.D.)	249.4±0.4	255.5±0.6	250.7±1.5	251.5±0.7	248.5±0.4
THICKNESS (mm+S.D)	2.344±0.008	2.414±0.010	2.368±0.019	2.397±0.632	2.399±0.494
HARDNESS (Kp+S.D.)	10.96±0.67	11.03±0.75	11.98±0.65	11.50±0.61	11.08±0.56
FRIABILITY (%)	0.67	0.56	0.46	0.43	0.30
DISINTEGRATION TIME	>30 min	95.17	48.33	29.83	30.17
RANGE		(75-120)	(38-77)	(28-31))	(29-31)
APPLIED PRESSURE (kg)	1457.8	1424.0	1472.2	1472.2	1472.2
RANGE	1419-1496	1398-1448	1448-1496	1448-1496	1448-1496

Table 17

Physical Properties of Dibasic Calcium Phosphate Dihydrate Tablets Containing Various Concentrations of Starch 1500(R) at Different Compression Pressures.

Compression pressure (kg) / Physical properties of tablets	Concentration (%)				
	0	0.5	1	2	5
500 WEIGHT (mg+S.D.)	249.2±0.7	249.0±1.5	255.5±0.5	155.7±0.9	254.3±0.6
THICKNESS (mm+S.D)	2.541±0.003	2.540±0.008	2.626±0.005	2.629±0.006	2.678±0.007
HARDNESS (Kp+S.D.)	2.91±0.61	2.86±0.18	2.84±0.49	2.43±0.70	2.14±0.92
FRIABILITY (%)	1.59	2.51	1.66	1.60	1.49
DISINTEGRATION TIME (SEC)	>30 min	>30 min	847.5	126	32.67
RANGE			(640-960)	(67-179)	(27-40)
APPLIED PRESSURE (kg)	506.8	458.6	446.5	458.6	506.8
RANGE	482-531	437-482	434-458	434-482	482-531
1000 WEIGHT (mg+S.D.)	247.2±1.0	247.1±1.0	256.5±1.2	254.6±1.1	257.0±0.7
254.3+0.6 (mm+S.D)	2.386±0.009	2.492±0.005	2.473±0.007	2.523±0.00	2.678±0.007
HARDNESS (Kp+S.D.)	6.85±0.84	4.90±0.17	6.16±0.42	6.44±0.55	2.14±0.92
FRIABILITY (%)	0.82	1.29	0.73	0.73	1.49
DISINTEGRATION TIME (SEC)	>30 min	>30 min	>30 min	274	32.67
RANGE				(110-60)	(27-40)
APPLIED PRESSURE (kg)	1018.5	941.3	955.7	984.7	1001.6
RANGE	989-1047	917-965	917-994	965-1004	965-1037
1500 WEIGHT (mg+S.D.)	249.4±0.4	255.9±1.7	254.6±0.7	255.2±0.5	254.7±0.6
THICKNESS (mm+S.D)	2.344±0.008	2.413±0.011	2.417±0.007	2.429±0.004	2.490±0.008
HARDNESS (Kp+S.D.)	10.96±0.67	13.72±0.76	11.94±0.74	12.43±0.76	10.99±0.40
FRIABILITY (%)	0.67	0.57	0.56	0.43	0.42
DISINTEGRATION TIME (SEC)	>30 min	>30 min	>30 min	644.67	53.678
RANGE				(450-950)	(48-60)
APPLIED PRESSURE (kg)	1457.8	1481.9	1424.0	1472.2	1424.0
RANGE	1419-1496	1448-1515	1399-1448	1448-1496	1399-1448

Table 18

Physical Properties of α-Lactose Monohydrate Tablets Containing Various Concentrations of D_1 at Different Compression Pressures

Compression pressure (kg)	Physical properties of tablets	Concentration (%)				
		0	0.5	1	2	5
500	WEIGHT (mg±S.D.)	269.4±1.8	258.3±0.8	251.6±2.2	257.3±1.7	255.0±1.4
	THICKNESS (mm±S.D)	4.114±0.019	3.872±0.014	3.772±0.014	3.863±0.009	3.807±0.017
	HARDNESS (Kp±S.D.)	3.08±0.60	3.80±0.39	3.25±0.87	3.41±0.734	2.85±0.70
	FRIABILITY (%)	1.60	1.28	1.35	1.36	1.37
	DISINTEGRATION TIME (SEC)	145.83	11	26.33	27.17	39.83
	RANGE	(135-175)	(25-32)	(25-28)	(25-30)	(35-43)
	APPLIED PRESSURE (kg)	532.9	528.49	492.63	501.64	515.0
	RANGE	501-564	519-537	447-537	465-537	492-537
1000	WEIGHT (mg±S.D.)	269.7±3.8	258.8±0.9	251.0±1.5	261.6±1.6	254.1±1.5
	THICKNESS (mm±S.D)	3.895±0.015	3.668±0.015	3.551±0.014	3.690±0.016	3.590±0.031
	HARDNESS (Kp±S.D.)	6.01±0.83	8.46±0.99	8.24±0.48	8.91±0.87	6.67±0.58
	FRIABILITY (%)	0.90	0.63	0.61	0.57	0.63
	DISINTEGRATION TIME (SEC)	239.53	76.67	64.5	64.33	61.83
	RANGE	(205-270)	(65-88))	(60-70)	(50-72)	(59-65)
	APPLIED PRESSURE (kg)	1043.4	985.2	1030.0	1030.0	998.7
	RANGE	1003-1083	895-1074	985-1074	985-1074	940-1056
1500	WEIGHT (mg±S.D.)	274.5±1.9	246.5±1.1	242.9±1.4	243.9±1.4	248.3±1.3
	THICKNESS (mm±S.D)	3.803±0.030	3.463±0.019	3.421±0.009	3.426±0.020	3.482±0.018
	HARDNESS (Kp±S.D.)	9.15±1.62	7.77±0.86	8.17±0.56	9.31±0.34	8.54±0.52
	FRIABILITY (%)	0.52	0.59	0.61	0.54	0.55
	DISINTEGRATION TIME (SEC)	419.17	139.33	103.67	103.00	107.33
	RANGE	(370-430)	(120-152)	(95-130)	(88-113)	(80-119)
	APPLIED PRESSURE (kg)	1648.0	1477.8	1388.3	1477.8	1455.4
	RANGE	1540-1755	1433-1522	1343-1433	1433-1522	1388-1522

Table 19

Physical Properties of α-Lactose Monohydrate Tablets Containing Various Concentrations of D_2 at Different Compression Pressures

Compression pressure (kg) \ Physical properties of tablets	Concentration (%)				
	0	0.5	1	2	5
500 WEIGHT (mg+S.D.)	269.4±1.8	251.3±2.5	2.47±2.72	253.7±2.1	255.9±2.0
THICKNESS (mm+S.D)	4.114±0.019	3.805±0.014	3.721±0.016	3.835±0.010	3.836±0.022
HARDNESS (Kp+S.D.)	3.08±0.60	2.35±1.07	3.98±0.57	3.07±0.534	2.50±0.58
FRIABILITY (%)	1.60	1.70	1.39	1.76	1.94
DISINTEGRATION TIME (SEC)	145.83	42.5	32.33	35.67	463.33
RANGE	(135-175)	(37-47)	(29-36)	(31-41)	(250-660)
APPLIED PRESSURE (kg)	532.9	492.6	501.63	497.14	447.8
RANGE	501-564	447-537	447-555	456-537	429-465
1000 WEIGHT (mg+S.D.)	269.7±3.8	247.4±2.6	249.4±1.2	255.7±2.0	247.3±3.1
THICKNESS (mm+S.D)	3.895±0.015	3.538±0.021	3.566±0.011	3.632±0.023	3.550±0.025
HARDNESS (Kp+S.D.)	6.01±0.83	6.78±0.76	7.04±0.53	7.81±0.46	6.86±0.66
FRIABILITY (%)	0.90	0.78	0.75	0.68	0.79
DISINTEGRATION TIME (SEC)	239.53	81.33	57.83	67.17	209.5
RANGE	(205-270)	(75-86))	(55-61)	(61-70)	(150-360)
APPLIED PRESSURE (kg)	1043.4	940.4	958.40	1039.0	1097.2
RANGE	1003-1083	895-985	904-1012	985-1092	107-1119
1500 WEIGHT (mg+S.D.)	274.5±1.9	254.2±1.6	256.2±1.6	248.2±2.1	251.5±1.8
THICKNESS (mm+S.D)	3.803±0.020	3.609±0.027	3.593±0.035	3.530±0.025	3.542±0.038
HARDNESS (Kp+S.D.)	9.15±1.62	9.02±0.70	10.25±0.49	8.92±0.49	9.55±0.55
FRIABILITY (%)	0.52	0.55	0.55	0.60	0.56
DISINTEGRATION TIME (SEC)	419.17	141.17	99.33	102.17	102.67
RANGE	(370-430)	(135-147)	(91-106)	(94-120)	(95-108)
APPLIED PRESSURE (kg)	1648.0	1486.8	1634.6	1433.1	1634.6
RANGE	1540-1755	1433-1540	1612-1657	1343-1522	1612-1657

Table 20

Physical Properties of α-Lactose Monohydrate Tablets Containing Various Concentrations of Ac-di-Sol(R) at Different Compression Pressures

Compression pressure (kg) \ Physical properties of tablets		Concentration(%)			
		0	0.5	1	2	5
500	WEIGHT (mg+S.D.)	269.4±1.8	250.8±1.0	242.9±2.5	244.8±2.9	249.4±1.5
	THICKNESS (mm+S.D)	4.114±0.019	3.780±0.009	3.682±0.019	3.685±0.023	3.754±0.018
	HARDNESS (Kp+S.D.)	3.08±0.60	2.94±0.776	2.68±0.877	3.09±1.064	3.15±0.49
	FRIABILITY (%)	1.60	1.29	1.53	1.41	1.37
	DISINTEGRATION TIME (SEC)	145.83	31.17	27.33	52.17	57.50
	RANGE	(135-175)	(29-33)	(25-30)	(49-55)	(50-80)
	APPLIED PRESSURE (kg)	532.9	501.69	492.63	501.64	492.6
	RANGE	501-564	465-537	447-537	447-555	447-537
1000	WEIGHT (mg+S.D.)	269.7±3.8	246.8±1.8	245.9±1.0	248.7±2.8	250.1±2.2
	THICKNESS (mm+S.D)	3.895±0.015	3.518±0.019	3.508±0.011	3.552±0.026	3.582±0.014
	HARDNESS (Kp+S.D.)	6.01±0.83	7.80±0.61	7.47±0.39	7.79±0.484	7.08±0.44
	FRIABILITY (%)	0.90	0.63	0.65	0.66	0.62
	DISINTEGRATION TIME (SEC)	239.53	14.33	16.83	36.5	52.5
	RANGE	(205-270)	(13-16)	(15-19)	(34-40)	(45-75)
	APPLIED PRESSURE (kg)	1043.4	1052.4	1030.0	1043.4	962.8
	RANGE	1003-1083	985-119	985-1074	985-1101	895-1030
1500	WEIGHT (mg+S.D.)	274.5±1.9	264.4±1.6	245.0±3.0	235.7±1.7	248.3±1.9
	THICKNESS (mm+S.D)	3.803±0.020	3.487±0.034	3.451±0.028	3.482±0.026	3.502±0.027
	HARDNESS (Kp+S.D.)	9.15±1.62	9.90±0.53	9.64±0.74	9.76±0.874	9.66±0.41
	FRIABILITY (%)	0.52	0.50	0.50	0.46	0.50
	DISINTEGRATION TIME (SEC)	419.17	33.53	26.67	24.83	43
	RANGE	(370-430)	(32-35)	(25-28)	(22-29)	(40-46)
	APPLIED PRESSURE (kg)	1648.0	1500.2	1545.0	1545.0	1522.6
	RANGE	1540-1755	1388-1612	1477-1612	1477-1612	1433-1612

Table 21

Physical Properties of α-Lactose Monohydrate Tablets Containing Various Concentrations of Corn Starch at Different Compression Pressures

Compression pressure (kg)	Physical properties of tablets	Concentration (%)				
		0	0.5	1	2	5
500	WEIGHT (mg±S.D.)	269.4±1.8	260.1±1.2	255.4±2.7	257.0±2.9	250.6±1.0
	THICKNESS (mm±S.D)	4.114±0.019	3.962±0.009	3.867±0.016	3.922±0.015	3.847±0.012
	HARDNESS (Kp±S.D.)	3.08±0.60	2.44±0.72	2.81±0.94	2.24±0.904	1.04±0.65
	FRIABILITY (%)	1.60	1.86	1.63	1.81	2.37
	DISINTEGRATION TIME (SEC)	145.83	66	58.5	56	60.5
	RANGE	(135-175)	(60-70)	(55-61)	(48-60)	(55-70)
	APPLIED PRESSURE (kg)	532.9	524.09	510.53	524.04	483.7
	RANGE	501-564	492-555	474-546	501-546	447-519
1000	WEIGHT (mg±S.D.)	269.7±3.8	259.5±2.5	256.8±2.4	258.2±2.3	258.2±1.3
	THICKNESS (mm±S.D)	3.895±0.015	3.713±0.021	3.643±0.065	3.667±0.021	3.607±0.081
	HARDNESS (Kp±S.D.)	6.01±0.83	6.30±1.35	7.57±0.66	7.09±0.604	5.63±0.62
	FRIABILITY (%)	0.90	0.74	0.69	0.66	0.82
	DISINTEGRATION TIME (SEC)	239.53	130.83	74.33	45.5	39.2
	RANGE	(205-270)	(125-135)	(61-80)	(43-48)	(35-45)
	APPLIED PRESSURE (kg)	1043.4	967.3	1039.0	976.3	940.4
	RANGE	1003-1083	886-1047	985-1092	877-1074	895-985
1500	WEIGHT (mg±S.D.)	274.5±1.9	247.2±3.1	247.8±1.1	246.8±1.6	246.7±1.5
	THICKNESS (mm±S.D)	3.803±0.020	3.479±0.038	3.505±0.022	3.479±0.020	3.481±0.015
	HARDNESS (Kp±S.D.)	9.15±1.62	8.40±0.75	8.00±1.40	0.92±0.92	8.30±0.49
	FRIABILITY (%)	0.52	0.75	0.61	0.54	0.58
	DISINTEGRATION TIME (SEC)	419.17	232.2	115.17	29.5	28.33
	RANGE	(370-430)	(205-255)	(105-125)	(45-60)	(26-30)
	APPLIED PRESSURE (kg)	1648.0	1612.2	1477.8	1567.4	1388.3
	RANGE	1540-1755	1594-1630	1433-1522	1540-1594	1343-1433

Table 22

Physical Properties of α-Lactose Monohydrate Tablets Containing Various Concentrations of Explotab(®) at Different Compression Pressures

Compression pressure (kg) \ Physical properties of tablets		Concentration (%)				
		0	0.5	1	2	5
500	WEIGHT (mg+S.D.)	269.4±1.8	253.7±1.7	249.8±1.2	245.6±1.5	249.7±2.2
	THICKNESS (mm+S.D)	4.114±0.019	3.836±0.012	3.784±0.013	3.690±0.014	3.805±0.024
	HARDNESS (Kp+S.D.)	3.08±0.60	2.96±0.696	2.35±0.967	2.23±0.934	1.73±1.2
	FRIABILITY (%)	1.60	1.73	1.88	1.64	2.31
	DISINTEGRATION TIME (SEC)	145.83	10.83	17.53	28.57	40.67
	RANGE	(135-175)	(10-12)	(15-10)	(27-30)	(38-44)
	APPLIED PRESSURE (kg)	532.9	537.49	501.63	573.24	501.6
	RANGE	501-564	492-582	465-537	528-618	447-555
1000	WEIGHT (mg+S.D.)	269.7±3.8	249.2±2.3	248.1±2.5	249.2±1.4	247.6±1.4
	THICKNESS (mm+S.D)	3.895±0.015	3.600±0.030	3.581±0.014	3.566±0.011	33.564±0.014
	HARDNESS (Kp+S.D.)	6.01±0.83	6.12±0.71	5.63±1.04	5.87±0.724	5.45±0.90
	FRIABILITY (%)	0.90	0.82	0.89	0.80	0.93
	DISINTEGRATION TIME (SEC)	239.53	15.5	15.17	31.67	34.5
	RANGE	(205-270)	(15-16)	(14-16)	(27-45)	(25-40)
	APPLIED PRESSURE (kg)	1043.4	949.4	944.9	985.2	953.9
	RANGE	1003-1083	886-1012	895-994	9046-1065	904-1003
1500	WEIGHT (mg+S.D.)	274.5±1.9	256.7±1.4	251.1±1.5	253.0±1.4	247.1±0.8
	THICKNESS (mm+S.D)	3.803±0.020	3.617±0.024	3.520±0.044	3.554±0.024	3.473±0.017
	HARDNESS (Kp+S.D.)	9.15±1.62	7.65±1.22	8.18±1.61	8.52±1.31	7.66±1.29
	FRIABILITY (%)	0.52	0.71	0.64	0.57	0.56
	DISINTEGRATION TIME (SEC)	419.17	43.3	37.33	27.	32
	RANGE	(370-430)	(42-45)	(35-40)	(25-30)	(35-41)
	APPLIED PRESSURE (kg)	1648.0	1477.8	1567.4	1612.2	1567.4
	RANGE	1540-1755	1433-1522	1522-1612	1594-1630	1522-1612

Table 23

Physical Properties of α-Lactose Monohydrate Tablets Containing Various Concentrations of Kollidon CL(*) at Different Compression Pressures

Compression pressure (kg)	Physical properties of tablets	Concentration (%)				
		0	0.5	1	2	5
500	WEIGHT (mg+S.D.)	269.4±1.8	254.9±1.2	253.6±2.4	247.0±1.3	243.9±1.0
	THICKNESS (mm+S.D)	4.114±0.019	3.812±0.034	3.833±0.023	3727±0.009	3.799±0.015
	HARDNESS (Kp+S.D.)	3.08±0.60	4.29±0.70	3.65±0.71	3.44±0.56	1.27±0.86
	FRIABILITY (%)	1.60	1.26	1.39	1.33	1.63
	DISINTEGRATION TIME (SEC)	145.83	17	23.83	29.83	34.67
	RANGE	(135-175)	(15-19)	(2.787)	(24-40)	(31-40)
	APPLIED PRESSURE (kg)	532.9	492.6	492.6	470.2	47-9.2
	RANGE	501-564	447-537	447-537	447-492	447-510
1000	WEIGHT (mg+S.D.)	269.7±3.8	255.1±1.6	253.3±2.4	248.2±1.2	244.3±1.1
	THICKNESS (mm+S.D)	3.895±0.015	3.607±0.017	3.613±0.015	3.568±0.015	3.556±0.012
	HARDNESS (Kp+S.D.)	6.01±0.83	8.66±0.64	8.62±0.61	7.97±0.54	6.43±0.61
	FRIABILITY (%)	0.90	0.64	0.54	0.56	0.61
	DISINTEGRATION TIME (SEC)	239.53	22	17.83	16.83	22.5
	RANGE	(205-270)	(20-24)	(16-20)	(15-20)	(20-25)
	APPLIED PRESSURE (kg)	1043.4	985.2	1030.0	940.4	1030.0
	RANGE	1003-1083	895-1074	985-1074	895-985	985-1074
1500	WEIGHT (mg+S.D.)	274.5±1.9	252.8±0.8	250.0±2.0	246.6±2.2	247.7±1.8
	THICKNESS (mm+S.D)	3.803±0.020	3.575±0.020	3.550±0.028	3.520±0.031	3.599±0.029
	HARDNESS (Kp+S.D.)	9.15±1.62	10.65±0.76	10.40±0.57	10.11±0.54	8.29±0.69
	FRIABILITY (%)	0.52	0.48	0.49	0.48	0.47
	DISINTEGRATION TIME (SEC)	419.1749	27.8	12.67	27.17	22.5
	RANGE	(370-430)	(47-52)	(25-29)	(10-15)	(25-29)
	APPLIED PRESSURE (kg)	1648.0	1665.9	1584.3	1576.4	1433.1
	RANGE	1540-1755	1630-1701	1540-1630	1522-1630	1343-1522

Table 24

Physical Properties of α-Lactose Monohydrate Tablets Containing Various Concentrations of Nymcel(R) at Different Compression Pressures

Compression pressure (kg)	Physical properties of tablets	Concentration (%)				
		0	0.5	1	2	5
500	WEIGHT (mg+S.D.)	269.4±1.8	243.2±2.6	250.5±1.2	265.2±0.9	248.9±1.8
	THICKNESS (mm+S.D)	4.114±0.019	3.665±0.014	3.744±0.018	3.992±0.012	3.830±0.021
	HARDNESS (Kp+S.D.)	3.08±0.60	2.99±0.87	3.66±0.57	3.98±0.484	2.74±0.63
	FRIABILITY (%)	1.60	1.42	1.36	1.33	1.61
	DISINTEGRATION TIME (SEC)	145.83	11.83	20.17	63.83	135.83
	RANGE	(135-175)	(10-14)	(16-25)	(45-80)	(110-120)
	APPLIED PRESSURE (kg)	532.9	501.69	497.13	546.44	483.7
	RANGE	501-564	465-537	456-537	537-555	447-519
1000	WEIGHT (mg+S.D.)	269.7±3.8	243.4±1.9	250.0±1.6	247.1±1.4	250.5±1.9
	THICKNESS (mm+S.D)	3.895±0.015	3.470±0.017	3.510±0.024	3.546±0.021	3.582±0.017
	HARDNESS (Kp+S.D.)	6.01±0.83	7.37±1.00	7.59±1.10	7.30±1.264	6.81±1.29
	FRIABILITY (%)	0.90	0.62	0.60	0.58	0.47
	DISINTEGRATION TIME (SEC)	239.53	17.83	18.17	21	80.83
	RANGE	(205-270)	(16-20))	(17-20)	(15-25)	(70-90)
	APPLIED PRESSURE (kg)	1043.4	985.2	1074.8	1003.1	940.4
	RANGE	1003-1083	895-1074	985-1164	949-1056	895-985
1500	WEIGHT (mg+S.D.)	274.5±1.9	250.2±1.5	247.8±1.9	242.9±2.2	242.1±1.1
	THICKNESS (mm+S.D)	3.803±0.020	3.529±0.032	3.497±0.030	3.420±0.051	3.407±0.024
	HARDNESS (Kp+S.D.)	9.15±1.62	8.21±1.60	8.74±1.37	9.17±1.68	8.35±1.29
	FRIABILITY (%)	0.52	0.53	0.50	0.35	0.39
	DISINTEGRATION TIME (SEC)	419.17	40.83	27.17	23.5	53.17
	RANGE	(370-430)	(36-45)	(25-29)	(20-27)	(50-55)
	APPLIED PRESSURE (kg)	1648.0	1451.0	1477.8	1486.8	1464.4
	RANGE	1540-1755	1361-1540	1433-1522	1433-1540	1388-1540

Table 25

Physical Properties of -Lactose Monohydrate Tablets Containing Various Concentrations of Starch 1500(R) at Different Compression Pressures

Compression pressure (kg) / Physical properties of tablets	Concentration (%)				
	0	0.5	1	2	5
500 WEIGHT (mg+S.D.)	269.4±1.8	262.1±1.0	248.7±2.8	254.3±1.1	243.7±2.6
THICKNESS (mm+S.D)	4.114±0.019	3.925±0.012	3.745±0.214	3.867±0.023	3.705±0.012
HARDNESS (Kp+S.D.)	3.08±0.60	3.13±0.49	3.03±0.45	2.64±0.634	1.57±0.89
FRIABILITY (%)	1.60	1.51	1.66	2.04	1.77
DISINTEGRATION TIME (SEC)	145.83	30.33	19	31.5	26.67
RANGE	(135-175)	(27-35)	(16-25)	(28-35)	(24-30)
APPLIED PRESSURE (kg)	532.9	515.09	492.63	470.24	515.0
RANGE	501-564	492-537	447-537	447-492	465-564
1000 WEIGHT (mg+S.D.)	269.7±3.8	262.2±2.6	251.4±1.5	253.6±1.9	247.5±1.5
THICKNESS (mm+S.D)	3.895±0.015	3.722±0.058	3.571±0.016	3.612±0.018	3.574±0.011
HARDNESS (Kp+S.D.)	6.01±0.83	6.92±1.15	6.29±1.46	5.80±1.304	4.84±0.7
FRIABILITY (%)	0.90	0.67	0.74	0.67	0.81
DISINTEGRATION TIME (SEC)	239.53	119.73	48.5	33	32.5
RANGE	(205-270)	(88-150)	(41-56)	(30-36)	(29-36)
APPLIED PRESSURE (kg)	1043.4	985.2	1047.9	1074.8	958.4
RANGE	1003-1083	895-1074	1003-1092	985-1164	913-1003
1500 WEIGHT (mg+S.D.)	274.5±1.9	350.6±2.6	256.0±1.7	253.0±0.9	248.2±1.9
THICKNESS (mm+S.D)	3.803±0.020	3.505±0.043	3.615±0.032	3.563±0.022	3.537±0.035
HARDNESS (Kp+S.D.)	9.15±1.62	7.24±1.07	7.39±1.46	7.93±1.41	7.73±0.72
FRIABILITY (%)	0.52	0.53	0.55	0.46	0.47
DISINTEGRATION TIME (SEC)	419.17	177.33	81.5	66.17	44.17
RANGE	(370-430)	(172-187)	(74-88)	(60-70)	(35-52)
APPLIED PRESSURE (kg)	1648.0	1612.2	1513.7	1451.0	1486.8
RANGE	1540-1755	1567-1657	1433-1594	1361-1540	1433-1540

(b) Thickness of tablets

The average thickness and standard deviation of tablets for each formulation are shown in Tables 10-25. For dibasic calcium phosphate dihydrate system, thickness values tended to increase as the amount of disintegrant in formulation increased. In opposite, the decreasing of thickness values were found as compressional force increased.

For α-lactose monohydrate system, the increasing of thickness values as the amount of disintegrant increased were not found. However, the compressional force still effect thickness values in the same characteristic as dibasic calcium phosphate dihydrate.

(c) Hardness of Tablets

The average hardness and standard deviation of tablets are presented in Table 10-25. For dibasic calcium phosphate dihydrate and α-lactose monohydrate formulations, it was clearly observed that at the same compressional force, hardness values are influenced by concentration of disintegrant. At compressional force of 500 and 1,000 kg., there was a trend to decrease on hardness values as the amount of disintegrant in formulation increased except for α-lactose monohydrate formulation containing Ac-di-Sol$^{(R)}$, Nymcel$^{(R)}$ and D_2. At high compressional force of 1,500 kg, these effects were found in dibasic calcium phosphate dihydrate containing D_1,D_2, Kollidon CL$^{(R)}$ and α-lactose monohydrate containing Kollidon CL$^{(R)}$. For all cases, the dependency of tablet hardness on the compressional force were found.

(d) Friability of Tablets

The results of the friability of tablets of each

formula are shown in Table 10-25. It was noticed that friability decreased with increasing compressional force at all formulations studied. For all tablets commpressed at 500 kg, friability of gredter than 1% were observed. At compressional force of 1,000 and 1,500 kg the friability of all formulations, except for dibasic calcium phosphate dihydrate tablets containing D_2 5% or Starch 1500(R) 0.5 and 5% compressed at 1,000 kg, were within acceptable level of less than 1%. Friability of each formula wich below 1% was found to be insignificant different at the same compressional force (except at 500 kg).

(e) Disintegration time of Tablets

The results of disintegration time of tablet at different compressional forces are shown in Tables 10-17 and Figures 23-25 for dibasic calcium phosphate dihydrate formulations and in Tables 18-25 and Figures 26-28 for α-lactose monohydrate system.

1. Effect of disintegrant on disintegration time of dibasic calcium phosphate dihydrate formulations

At all compressional forces of most formulations, disintegration time were reduced significantly from the control formulations which showed no disintegration after 30 minutes. Ac-di-Sol(R), Explotab(R) and Nymcel(R) gave nearly instant disintegration of less than 100 seconds at all concentrations and compression pressures. Increase in compressional force and decrease in concentration of previously mentioned disintegrants resulted in increasing the disintegration time.

At 2 and 5% level of Kollidon CL(R), the instant disintegration of less than 25 seconds were found and at 0.5 and 1% level, there was a trend for disintegration time to increase

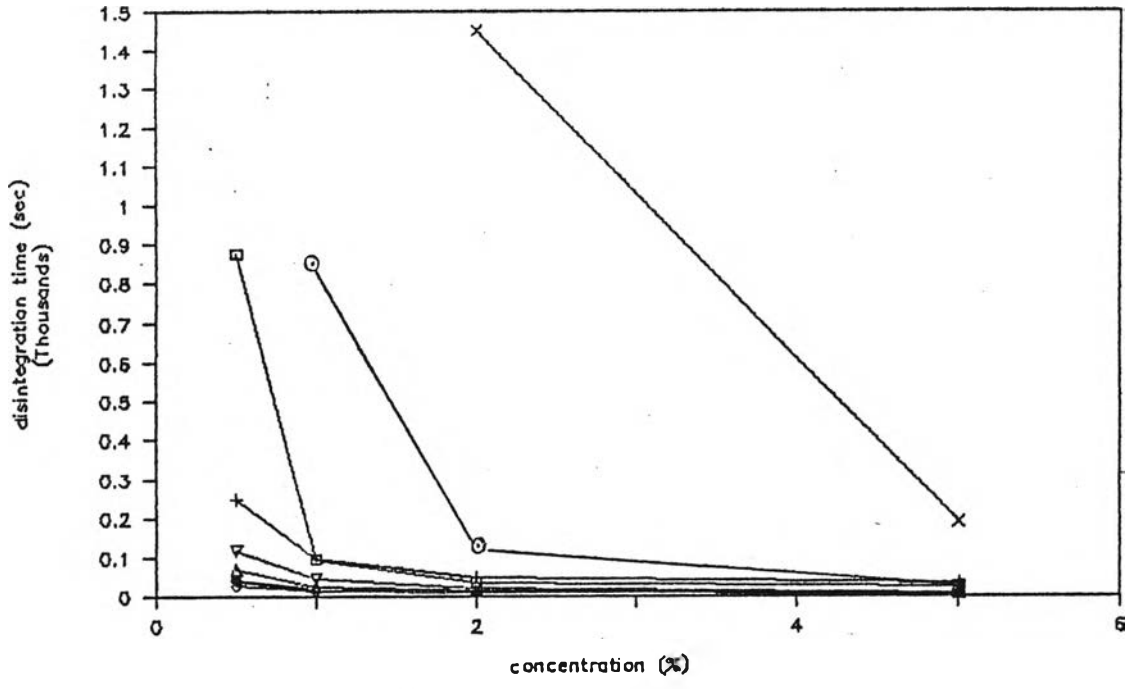


Figure 23. Disintegration time of various disintegrants as a function of concentration in dibasic calcium phosphate dihydrate tablet, at compressional force of 500 kg. ▫ D_1, + D_2, ◊ Ac-di-Sol, x corn starch, △ Explotab, ▽ Kollidon CL, ▼ Nymcel, ⊙ Starch 1500.

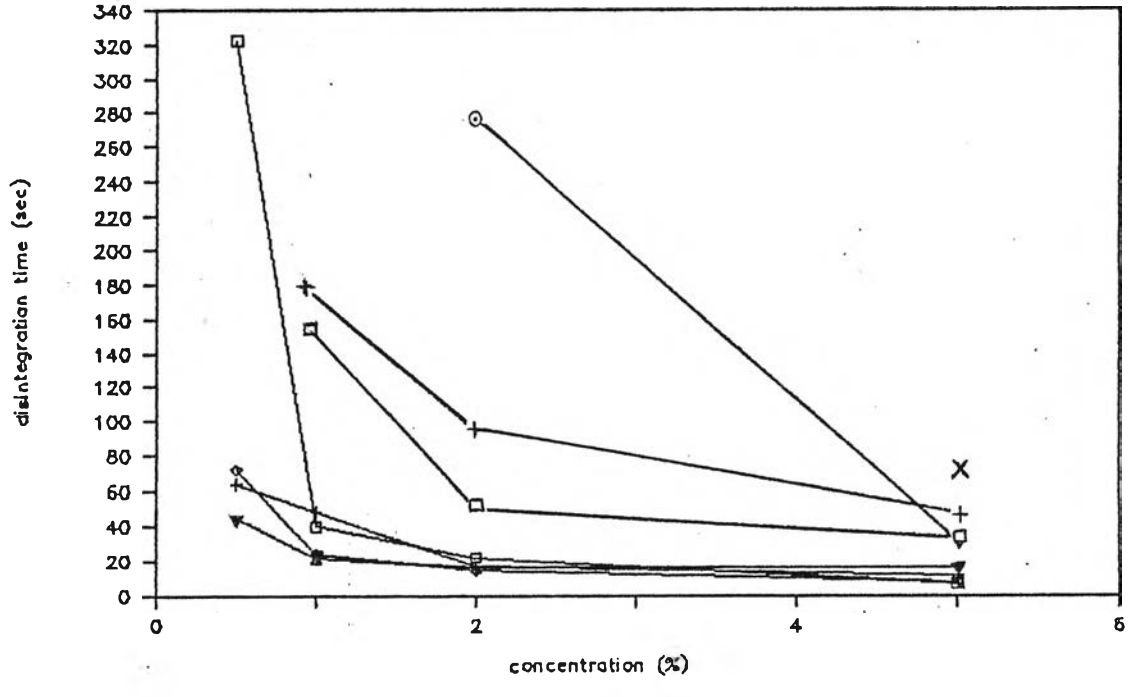


Figure 24. Disintegration time of various disintegrants as a function of concentration in dibasic calcium phosphate dihydrate tablet, at compressional force of 1,000 kg. ▫ D_1, + D_2, ◊ Ac-di-Sol, x corn starch, △ Explotab, ▽ Kollidon CL, ▼ Nymcel, ⊙ Starch 1500

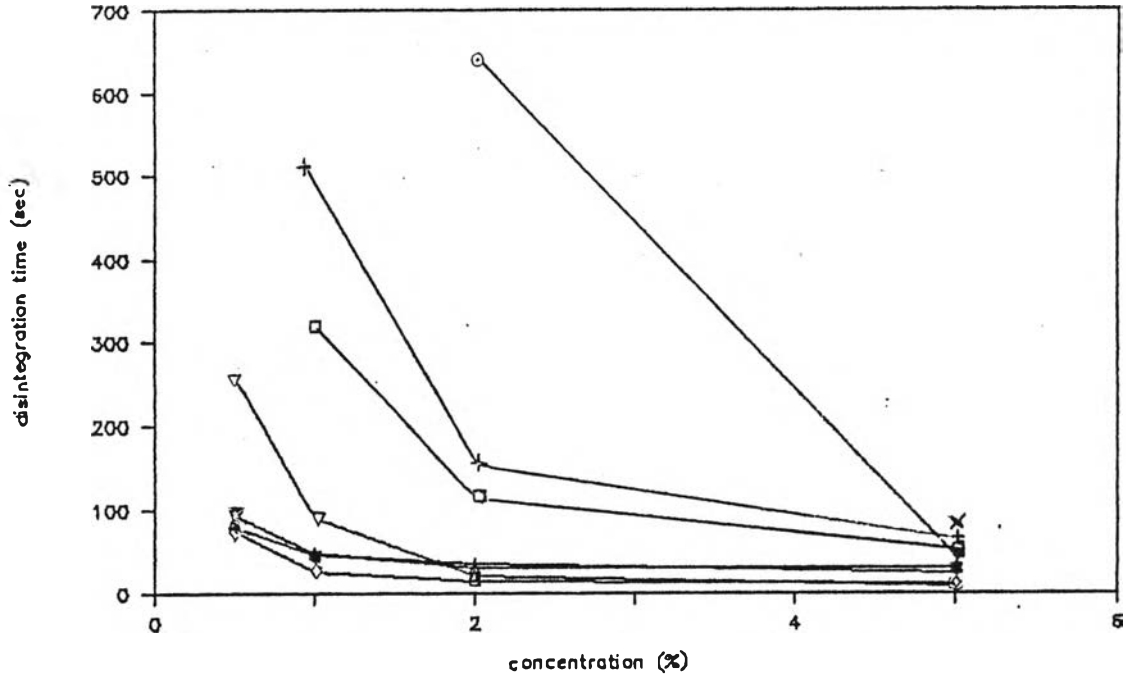


Figure 25. Disintegration time of various disintegrants as a function of concentration in dibasic calcium phosphate dihydrate tablet, at compressional force of 1,500 kg. ▫ D_1, + D_2, ◇ Ac-di-Sol, x corn starch, △ Explotab, ▽ Kollidon CL, ▼ Nymcel, ⊙ Starch 1500

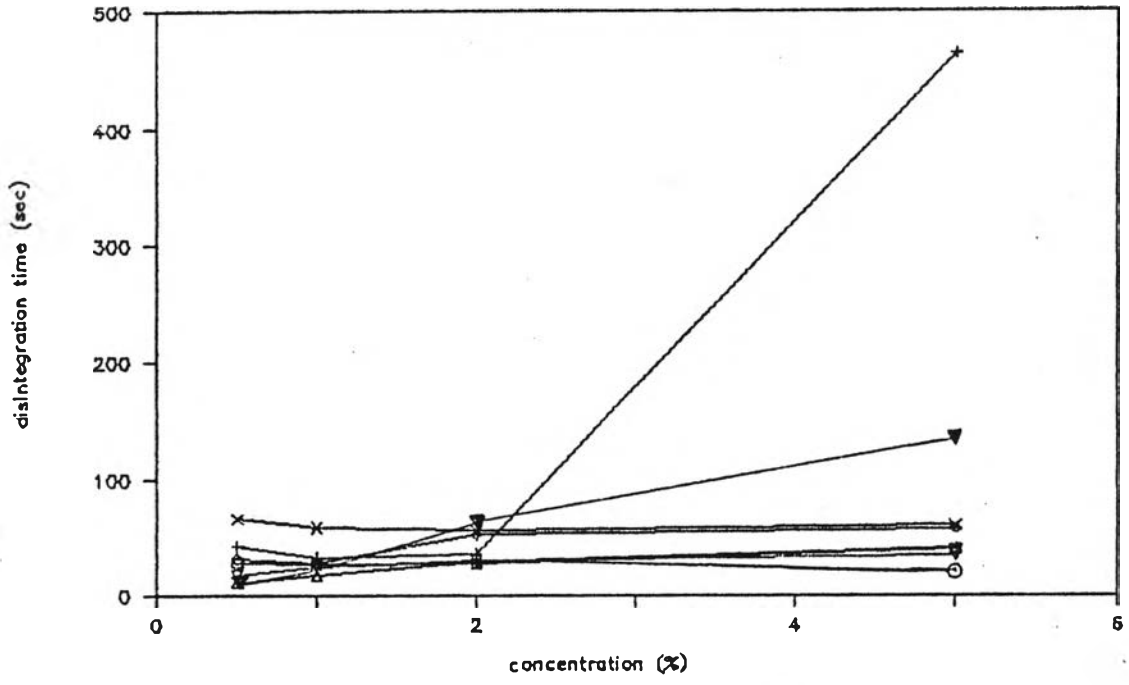


Figure 26. Disintegration time of various disintegrants as a function of concentration in α-lactose monohydrate tablet, at compressional force of 500 kg. □ D_1, + D_2, ◊ Ac-di-Sol, x corn starch, △ Explotab, ▽ Kollidon CL, ▼ Nymcel, ⊙ Starch 1500

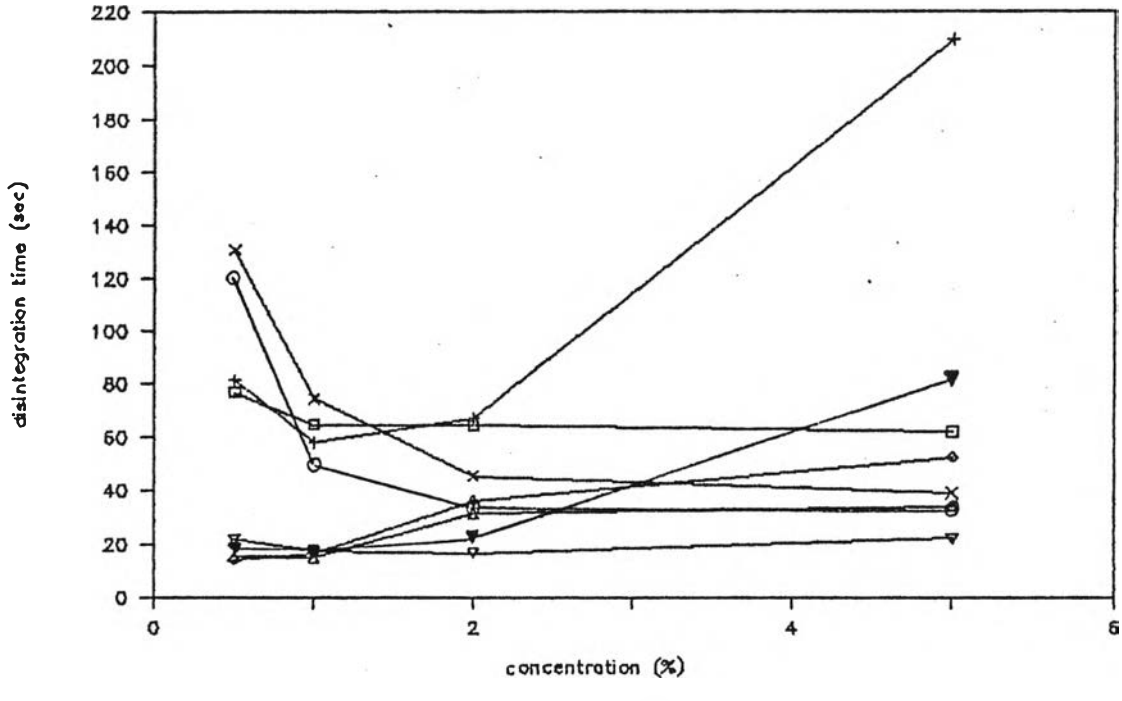


Figure 27. Disintegration time of various disintegrants as a function of concentration in α-lactose monohydrate tablet, at compressional force of 1000 kg. □ D_1, + D_2, ◊ Ac-di-Sol, x corn starch, △ Explotab, ▽ Kollidon CL, ▼ Nymcel, ⊙ Starch 1500

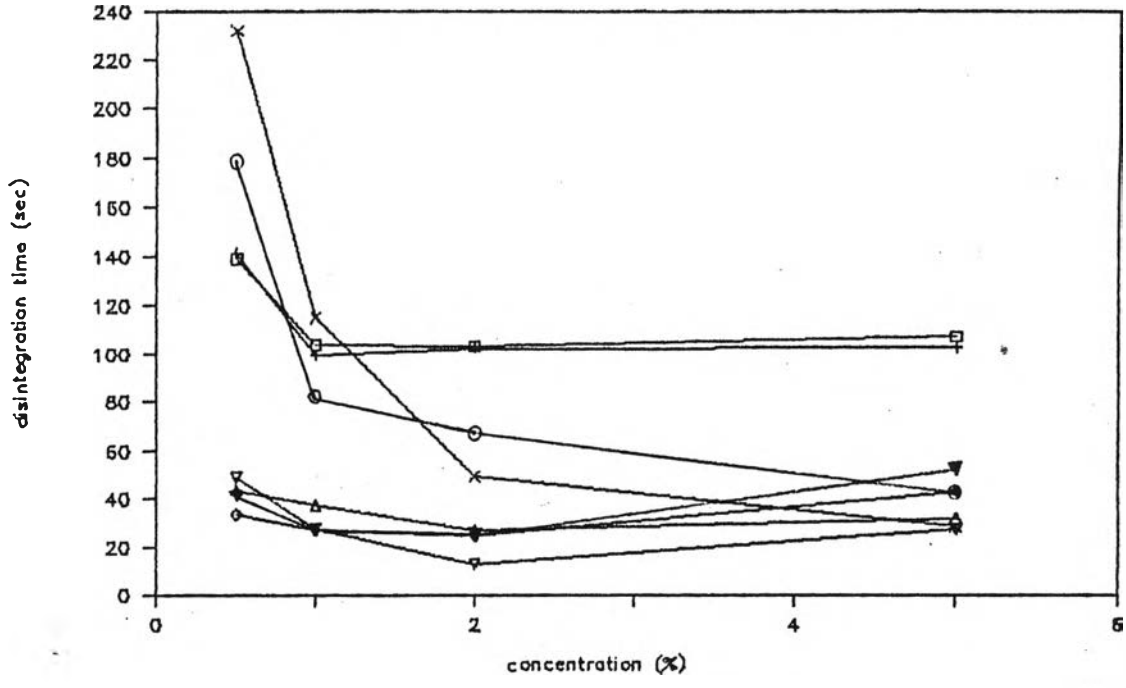


Figure 28. Disintegration time of various disintegrants as a function of concentration in α-lactose monohydrate tablet, at compressional force of 1500 kg. □ D_1, + D_2, ◇ Ac-di-Sol, x corn starch, △ Explotab, ▽ Kollidon CL, ▼ Nymcel, ⊙ Starch 1500

as compressional force increased. For D_1 and D_2 at 0.5% concentration, these were considered ineffective except for D_2 at compressional force of 500 kg. For all cases, as the amount of D_1 or D_2 increased the disintegration time of tablets were significantly reduced. On the other hand, an increasing compressional force directly related to a longer disintegration time.

Starch 1,500® was considered to be effective at concentration of > 2%, whereas at 5% was found for corn starch. Corn starch at 5% level showed different behaviors as compared with other disintegrants by disintegration time at compressional force of 1,000 and 1,500 kg were shorter than that 500 kg. For all compressional forces the efficiency of disintegrant to improve disintegration time were ranked as follows : Ac-di-Sol® > Nymcel® > Explotab® >Kollidon CL® > D_1 > D_2 >Starch 1500® > corn starch.

2. Effect of disintegrant on disintegration time of α -lactose monohydrate formulations

It was found that disintegration time of all formulations containing various disintegrants, at all compression pressures in this study were improved significantly from the control formulations. However, the disintegration behavior was quite different from dibasic calcium phosphate dihydrate formulations.

At compressional force of 500 kg., there was slightly different in disintegration time values among formulations except for D_2 and Nymcel® at 5% level, and the disintegration times of less than 70 seconds have been observed. In the case of formulation containing D_2 and Nymcel® at 5%

level, these showed significantly prolonged disintegration time ($p > 0.05$) than the others.

At compressional force of 1,000 kg the different in disintegration time between superdisintegrants and other disintegrants in this study was clearly seen. The dependency of prolonged disintegration time on concentration of disintegrant was still found for formulation containing D_2 and Nymcel(R) at 5% level. For formulations containing superdisintegrant such as Ac-di-Sol(R), Explotab(R), Kollidon CL(R) and Nymcel(R) (except at 5%), rapid disintegration time of less than 60 seconds were obtained. Formulations containing D_1, corn starch and Starch 1500(R) the disintegration time decreased when increase concentration.

At compressional force of 1,500 kg,dependency of prolonged disintegration time on concentration of D_2 and Nymcel(R) at 5% level were minimized. For Ac-di-Sol(R), Explotab(R), Kollidon CL(R) and Nymcel(R), the rapid disintegration time of less than 60 seconds were still observed. For corn starch and Starch 1500(R) the disintegration time still decreased when increase concentration. It was noticed that the disintegration time of D_1 and D_2 Formulation at various concentrations (< 14 seconds) appeared to be almost identical. The directly relationship between compression pressure and disintegration time of α-lactose monohydrate base formulations was found for D_1,D_2, corn starch and Starch 1,500(R),except D_2 and corn starch at 5% level which the inversely relationship presented.

(f) Water Uptake

Water penetration curves of various disintegrants at different concentrations in dibasic calcium phosphate dihydrate tablets compressed at three compressional forces are shown in Figures 29-40, and for α-lactose monohydrate tablets, these are presented in Figures 41-52. The efficiency of various disintegrants on the initial rate of water penetration in both diluent systems at different concentrations and compressional forces are summarizd in Tables 26-27. The penetration of water into tablets was classified according to type of disintegrant and diluent as follows :

1. D_1

1.1 Water insoluble diluent

Effect of D_1 on water penetration into tablets prepared from directly compressed dibasic calcium phosphate dihydrate at three compressional forces were compared with other disintegrants as given in Figures 29-40. In addition, the effect of compressional force are also shown in Figures 53-55. At 0.5% concentration of D_1, the occurence of water penetration didn't found. These figures depicts the influence of compressional force on the penetration rate of water into the tablets. It was clearly shown that an increase in compressional force produced decrease in penetration rate of water. Water uptake was markedly increased when increase amount of D_1. From these figures, it was noticed that both increasing compressional force and decreasing concentration of D_1, the lag time of penetration curve was increased.

1.2 Water soluble diluent

In the case of directly compressed α-lactose monohydrate system, D_1 behaved in a similar way as

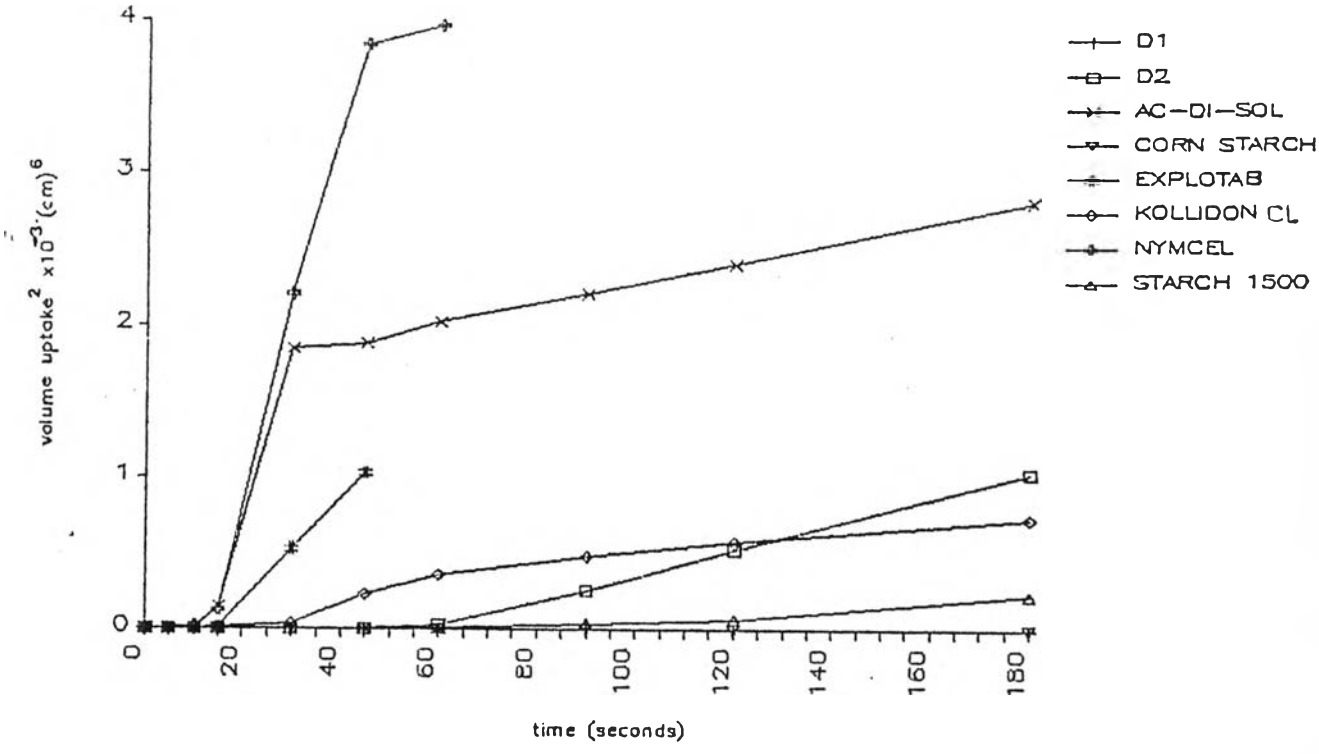


Figure 29. Water penetration curves of various disintegrants at 0.5% concentration in dibasic calcium phosphate dihydrate tablets, compressed at 500 kg.

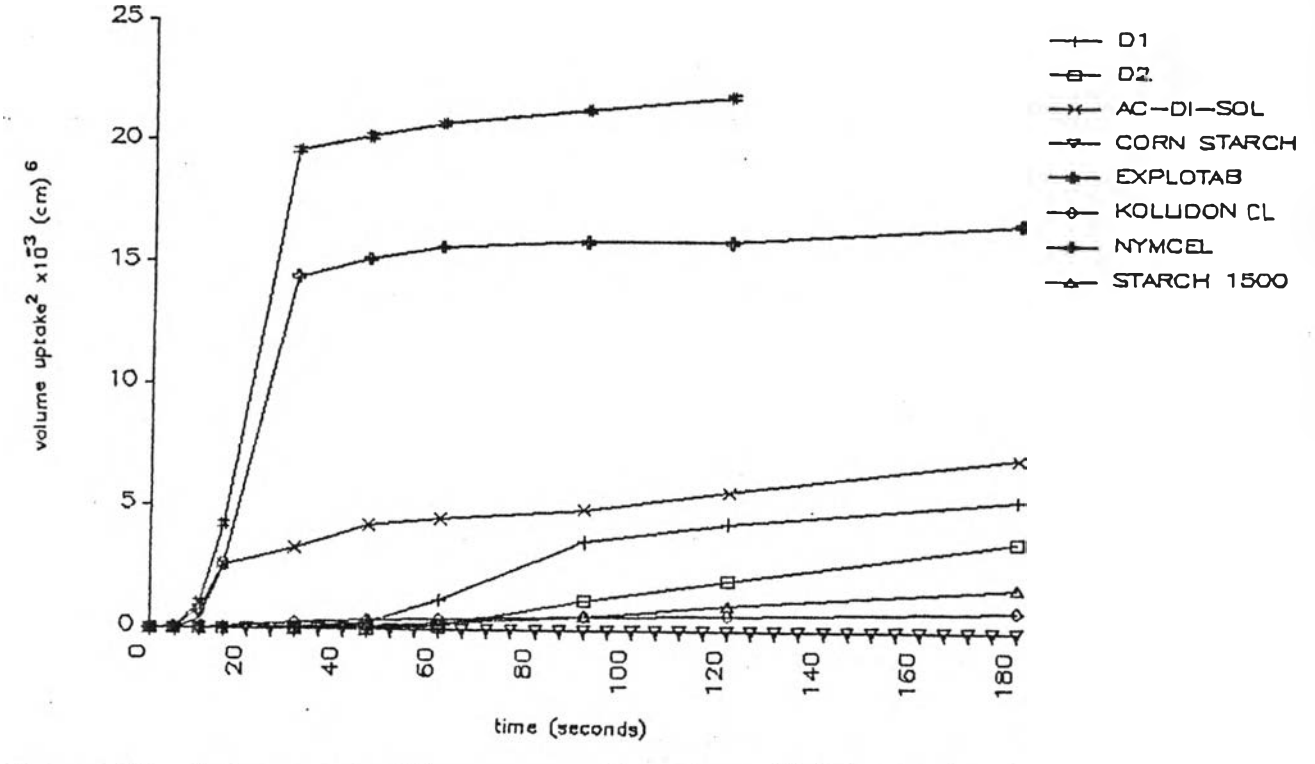


Figure 30. Water penetration curves of various disintegrants at 1% concentration in dibasic calcium phosphate dihydrate tablets, compressed at 500 kg.

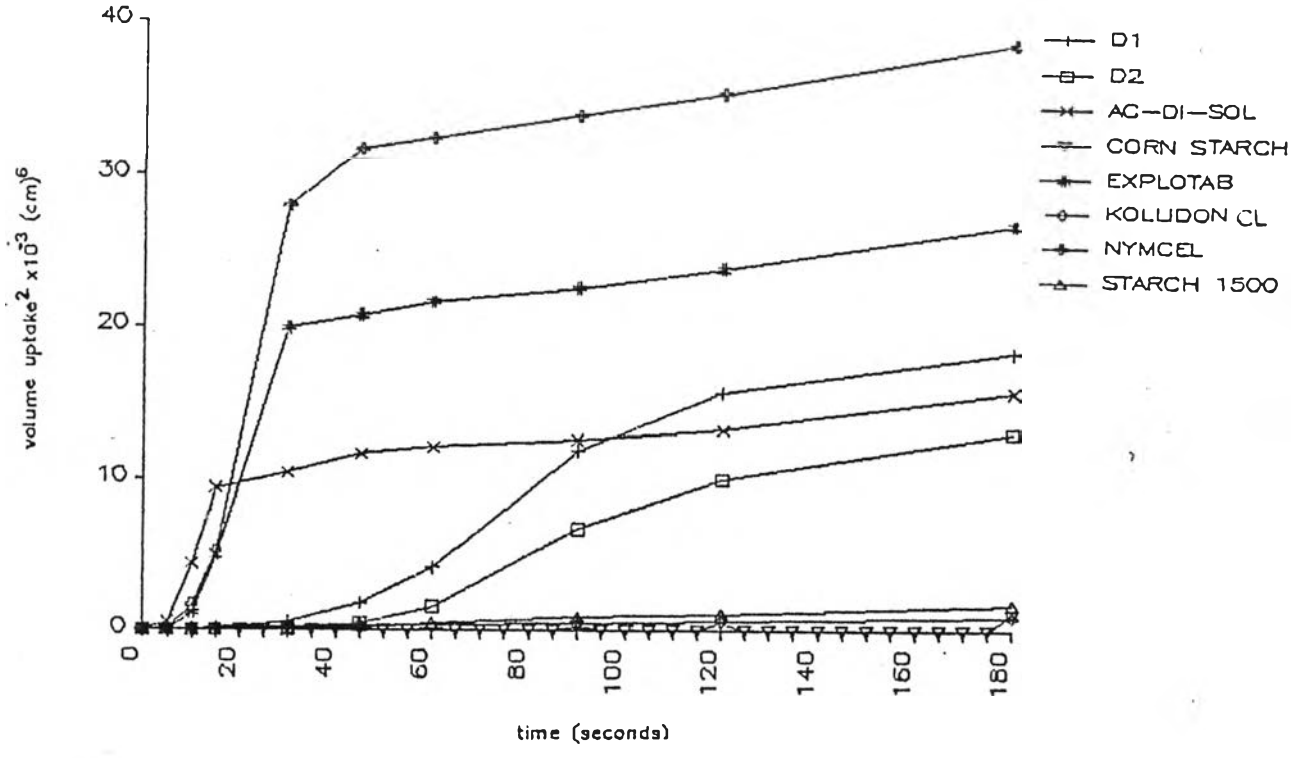


Figure 31. Water penetration curves of various disintegrants at 2% concentration in dibasic calcium phosphate dihydrate tablets, compressed at 500 kg.

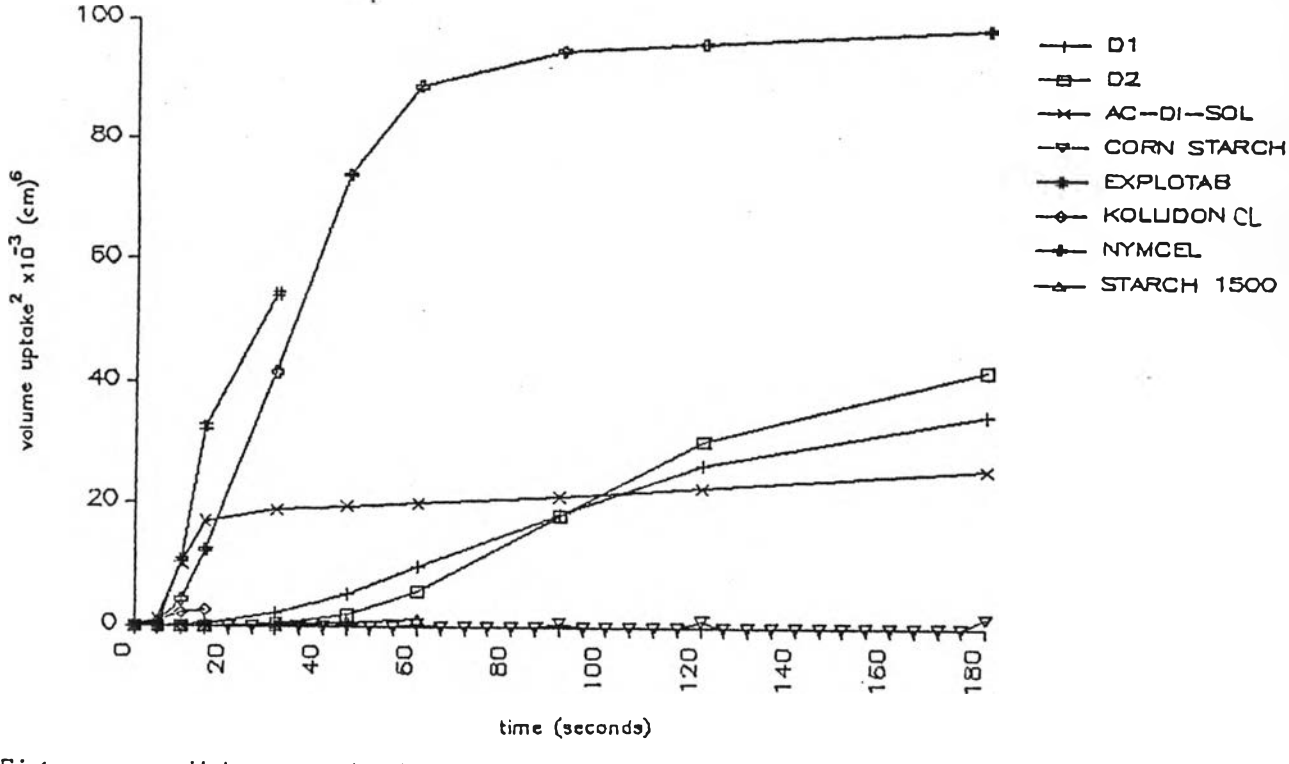


Figure 32, Water penetration curves of various disintegrants at 5% concentration in dibasic calcium phosphate dihydrate tablets, compressed at 500 kg.

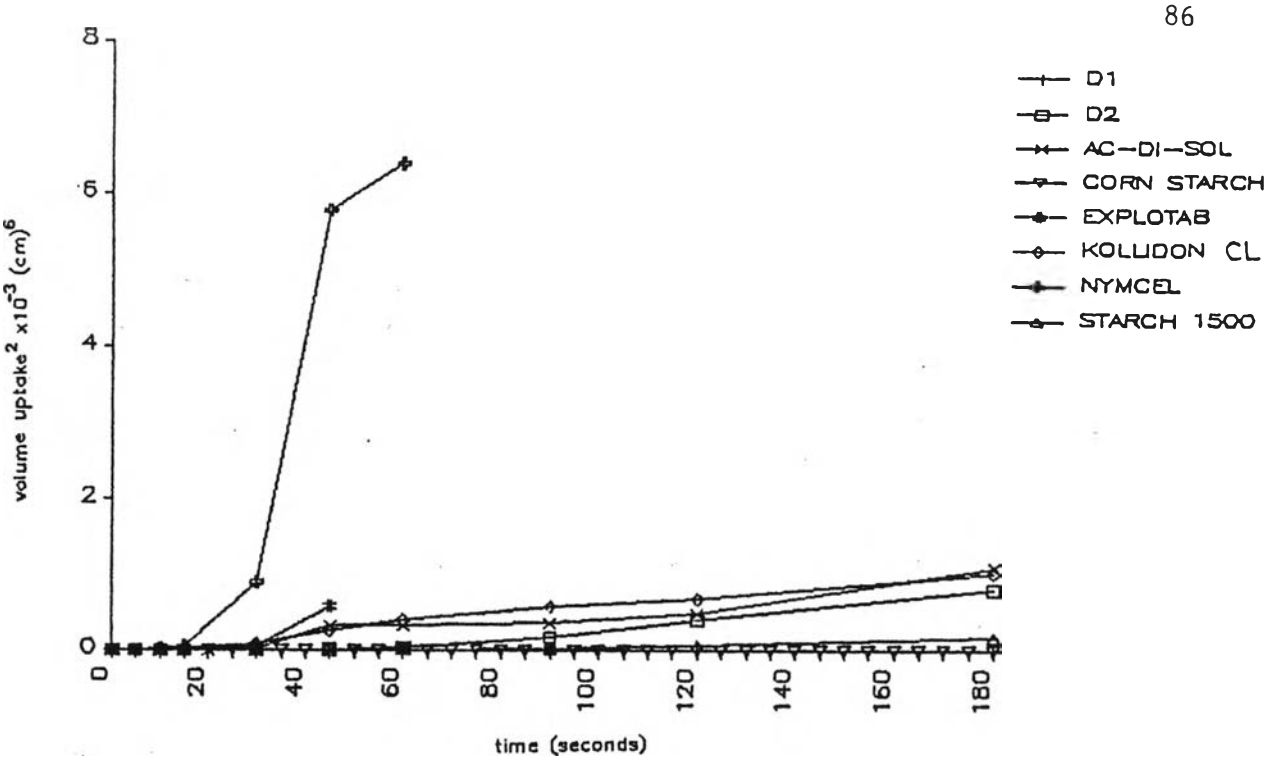


Figure 33 Water penetration curves of various disintegrants at 0.5% concentration in dibasic calcium phosphate dihydrate tablets, compressed at 1000 kg.

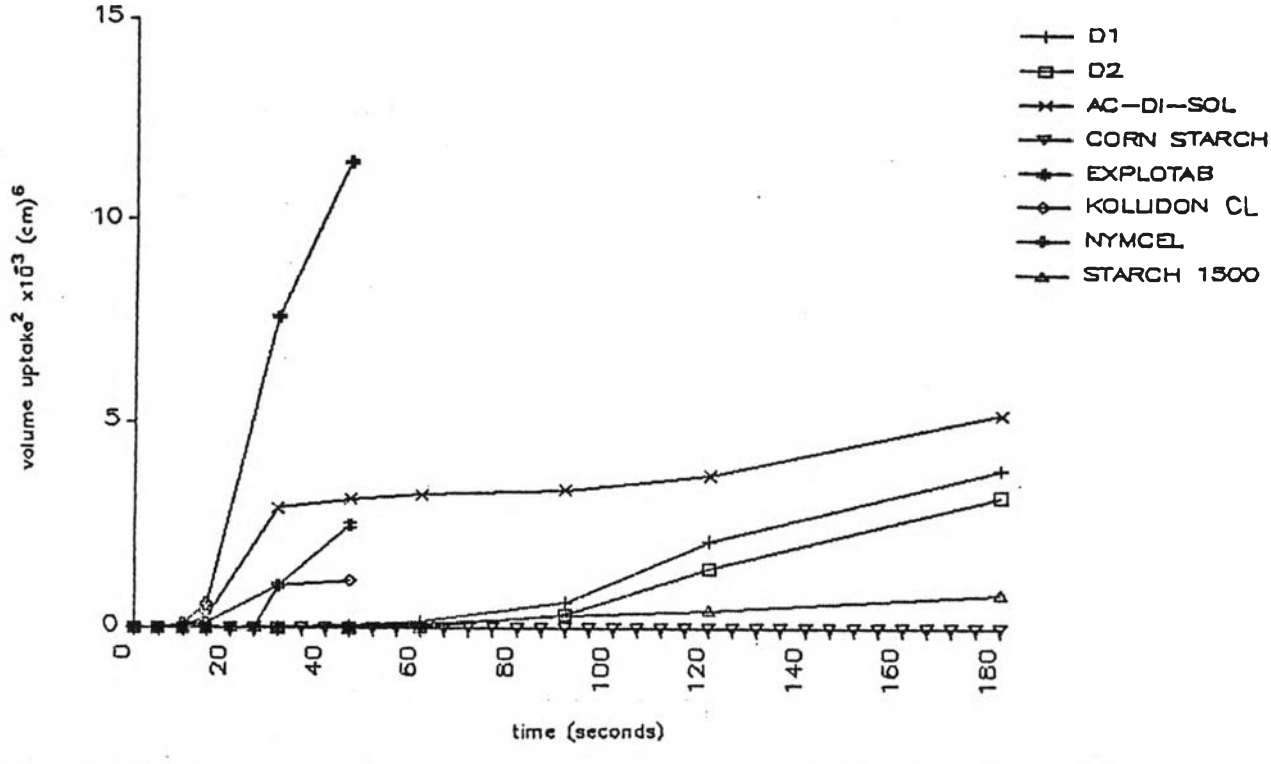


Figure 34 Water penetration curves of various disintegrants at 1% concentration in dibasic calcium phosphate dihydrate tablets, compressed at 1000 kg.

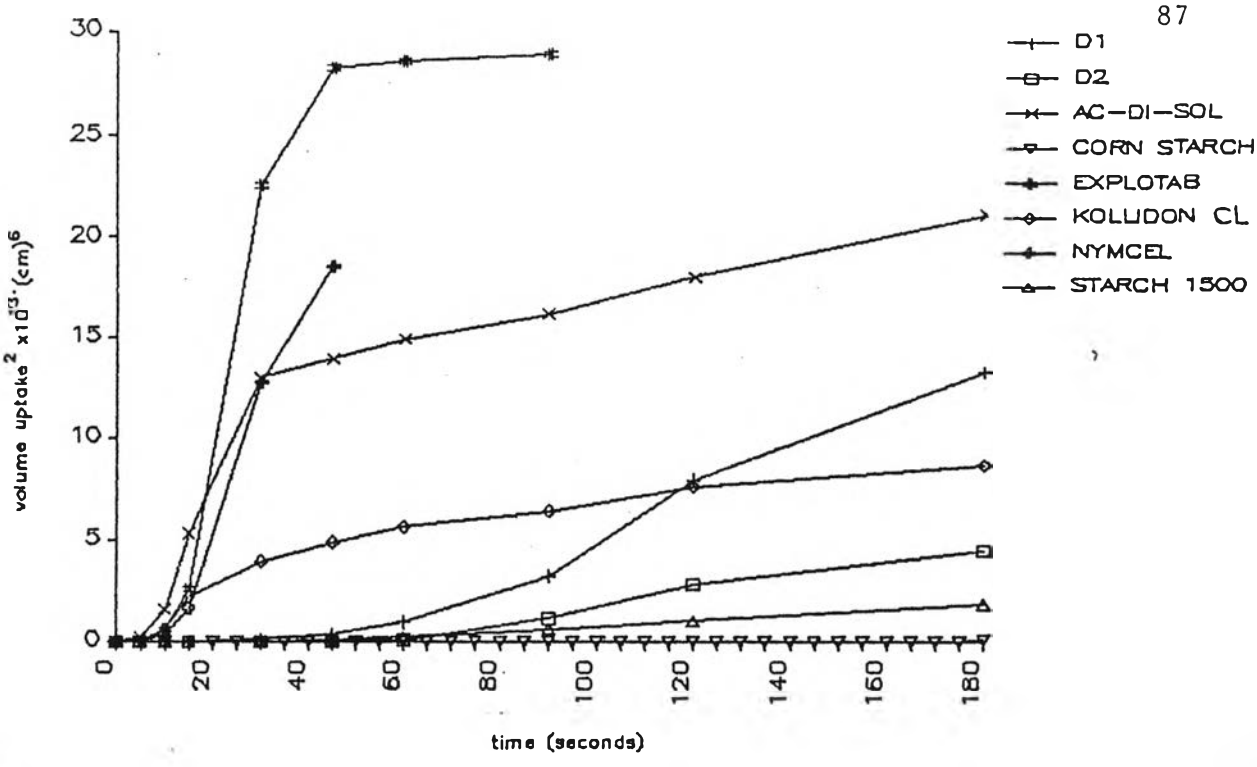


Figure 35 Water penetration curves of various disintegrants at 2% concentration in dibasic calcium phosphate dihydrate tablets, compressed at 1000 kg.

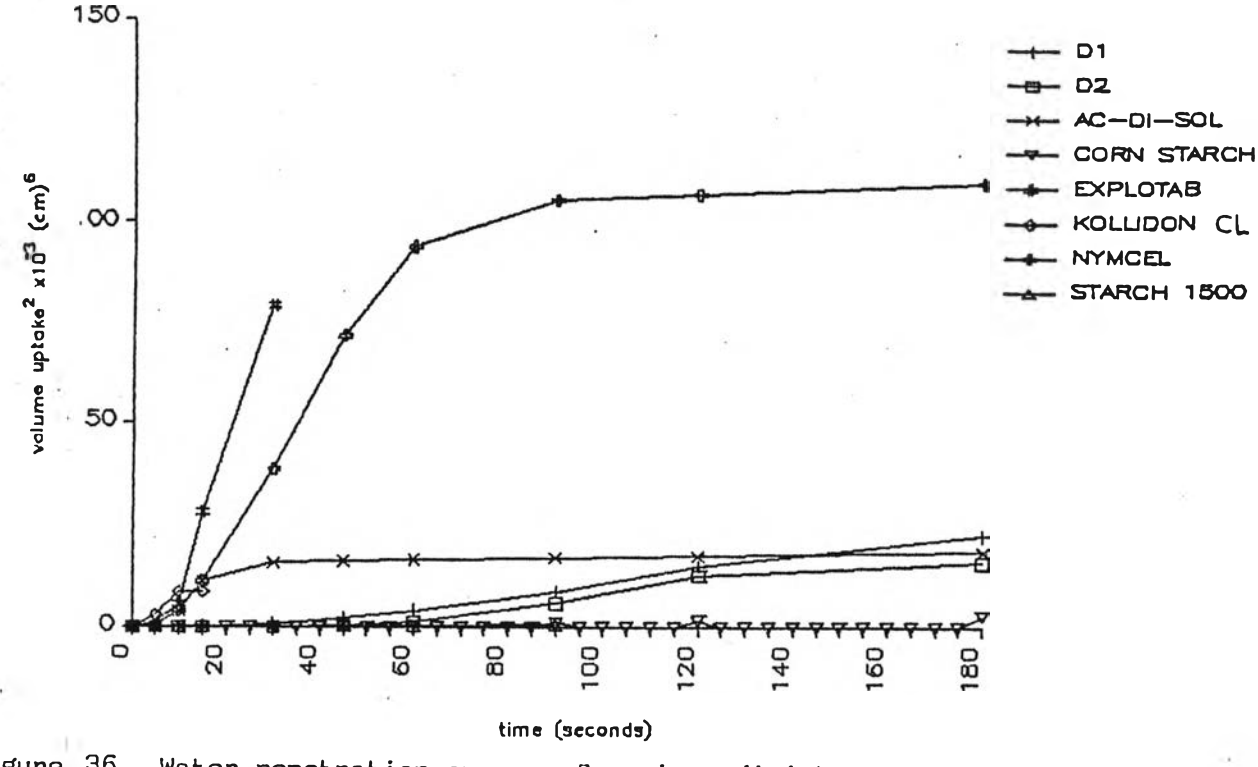


Figure 36 Water penetration curves of various disintegrants at 5% concentration in dibasic calcium phosphate dihydrate tablets, compressed at 1000 kg.

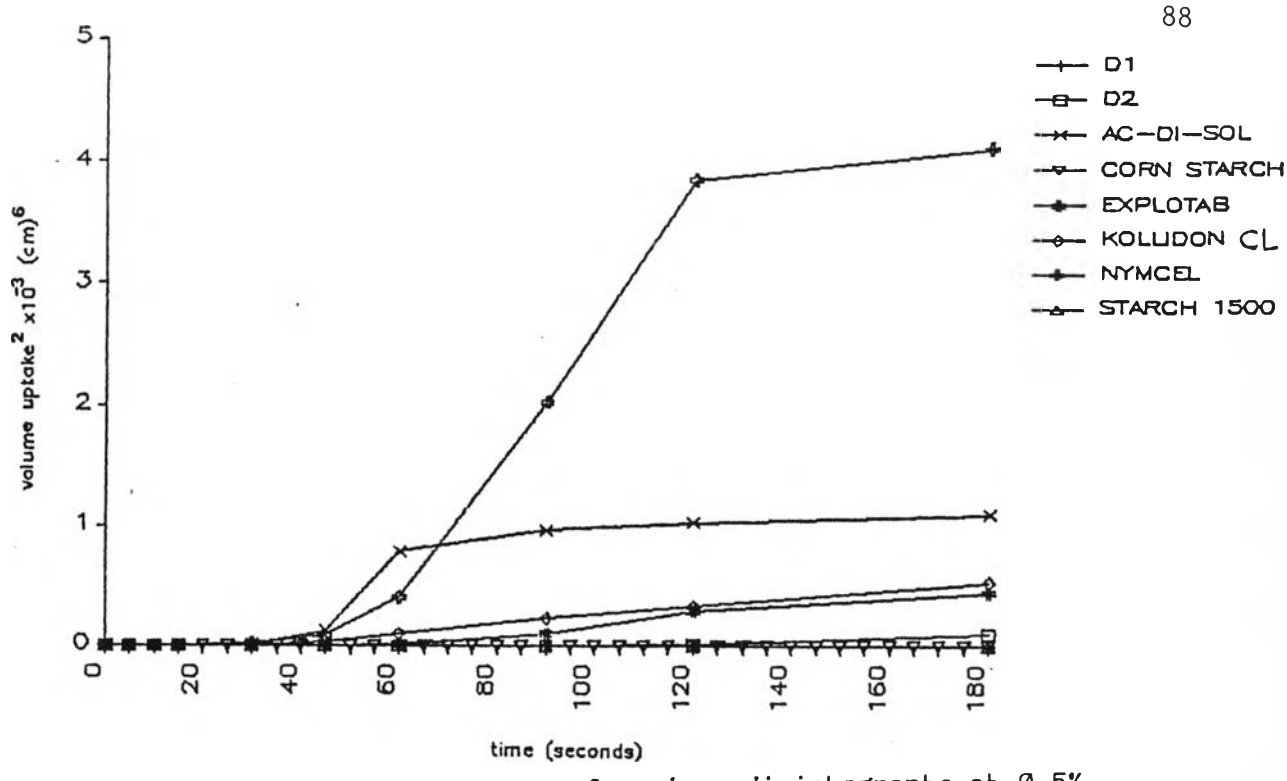


Figure 37 Water penetration curves of various disintegrants at 0.5% concentration in dibasic calcium phosphate dihydrate tablets, compressed at 1500 kg.

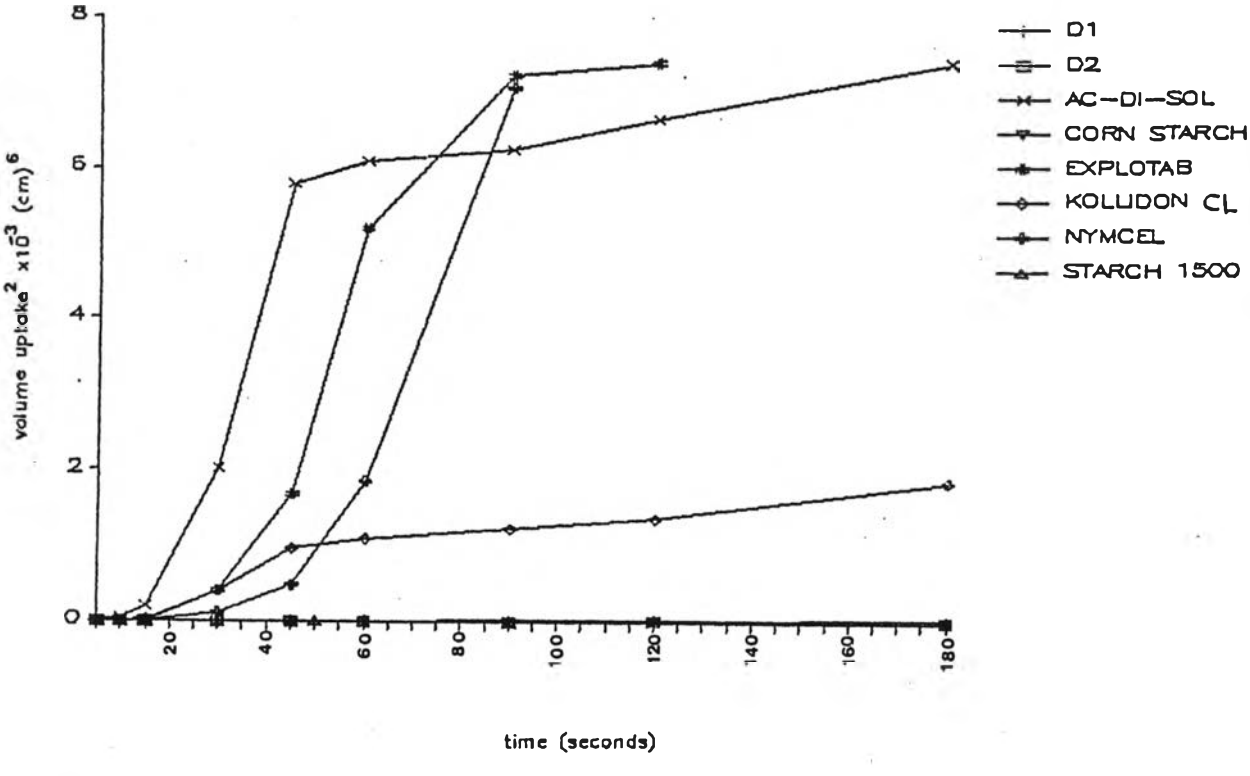


Figure 38 Water penetration curves of various disintegrants at 1% concentration in dibasic calcium phosphate dihydrate tablets, compressed at 1500 kg.

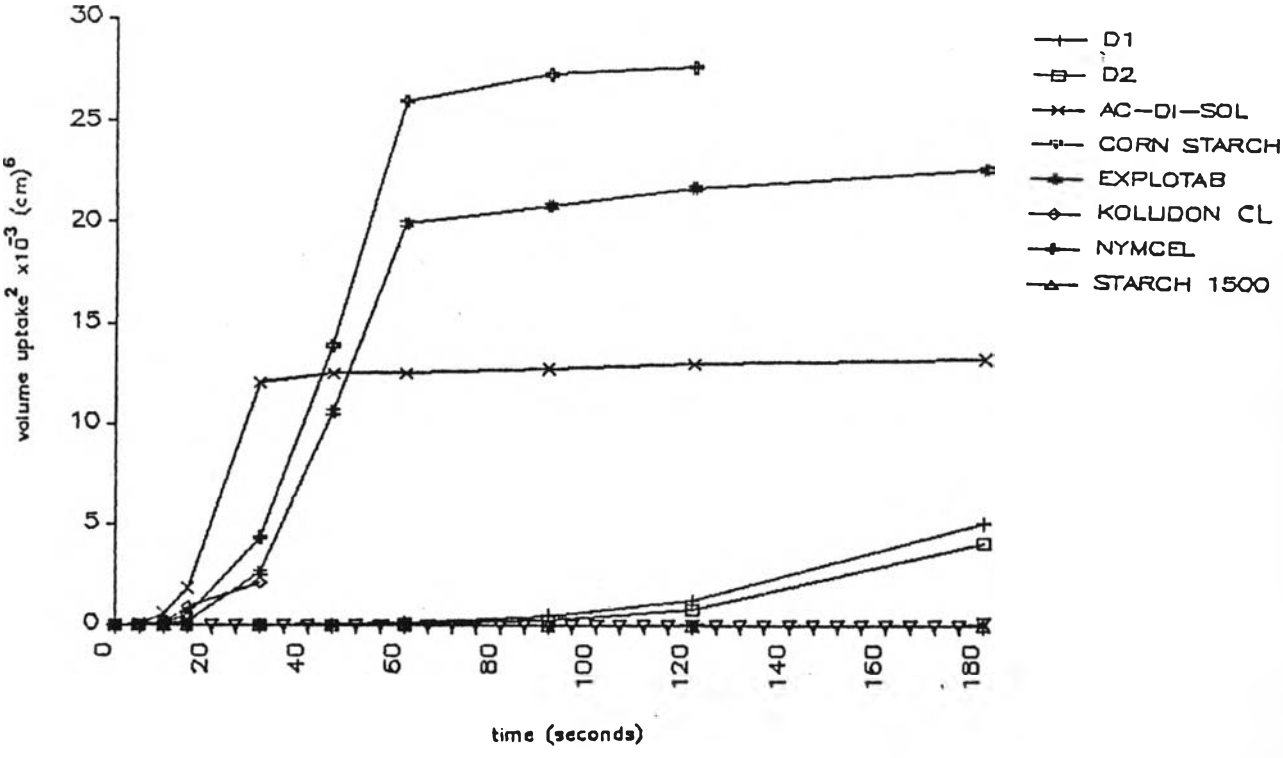


Figure 39 Water penetration curves of various disintegrants at 2% concentration in dibasic calcium phosphate dihydrate tablets, compressed at 1500 kg.

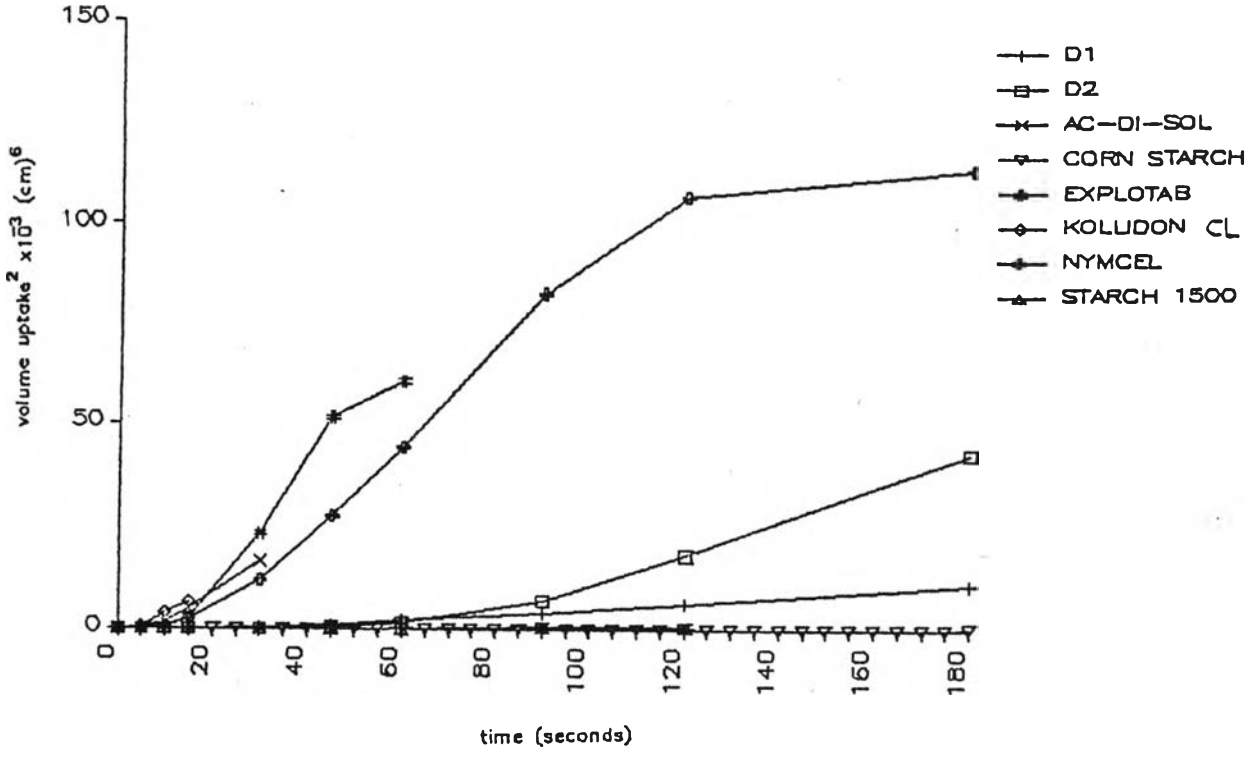


Figure 40 Water penetration curves of various disintegrants at 5% concentration in dibasic calcium phosphate dihydrate tablets, compressed at 1500 kg.

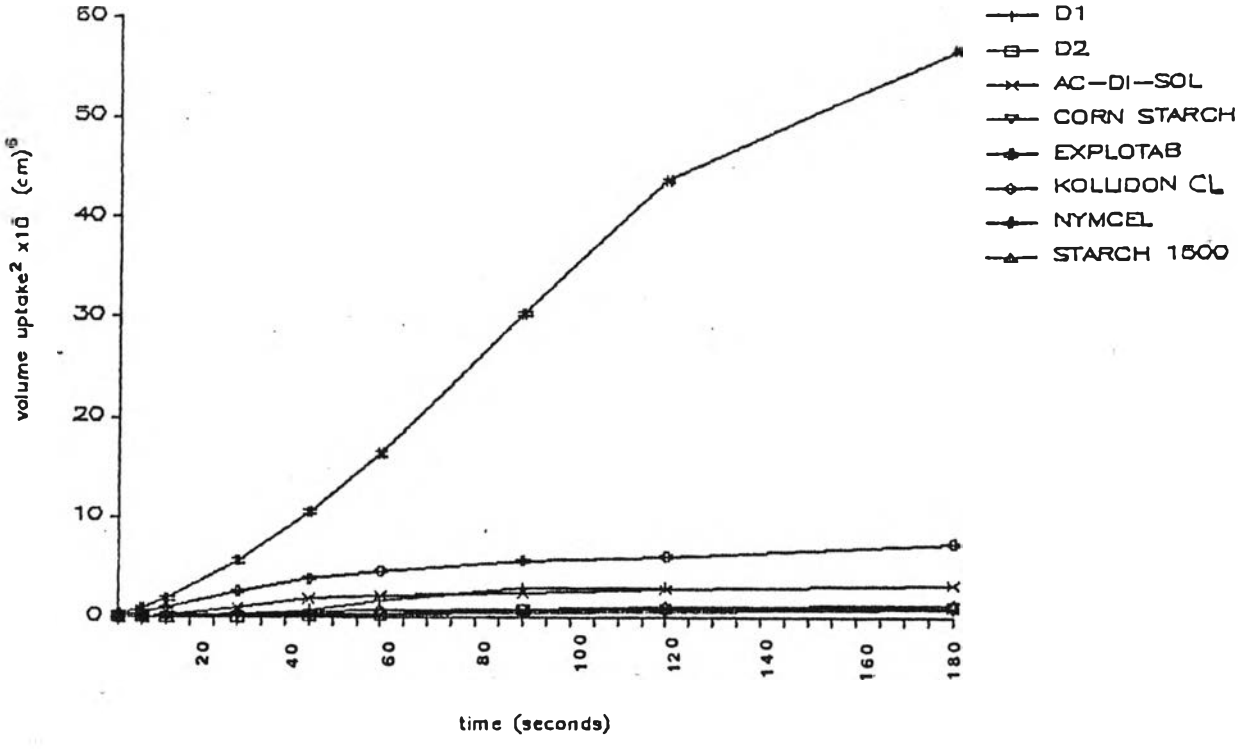


Figure 41 Water penetration curve of various disintegrants at 0.5% concentration in ∝-lactose monohydrate tablets, compressed at 500 kg.

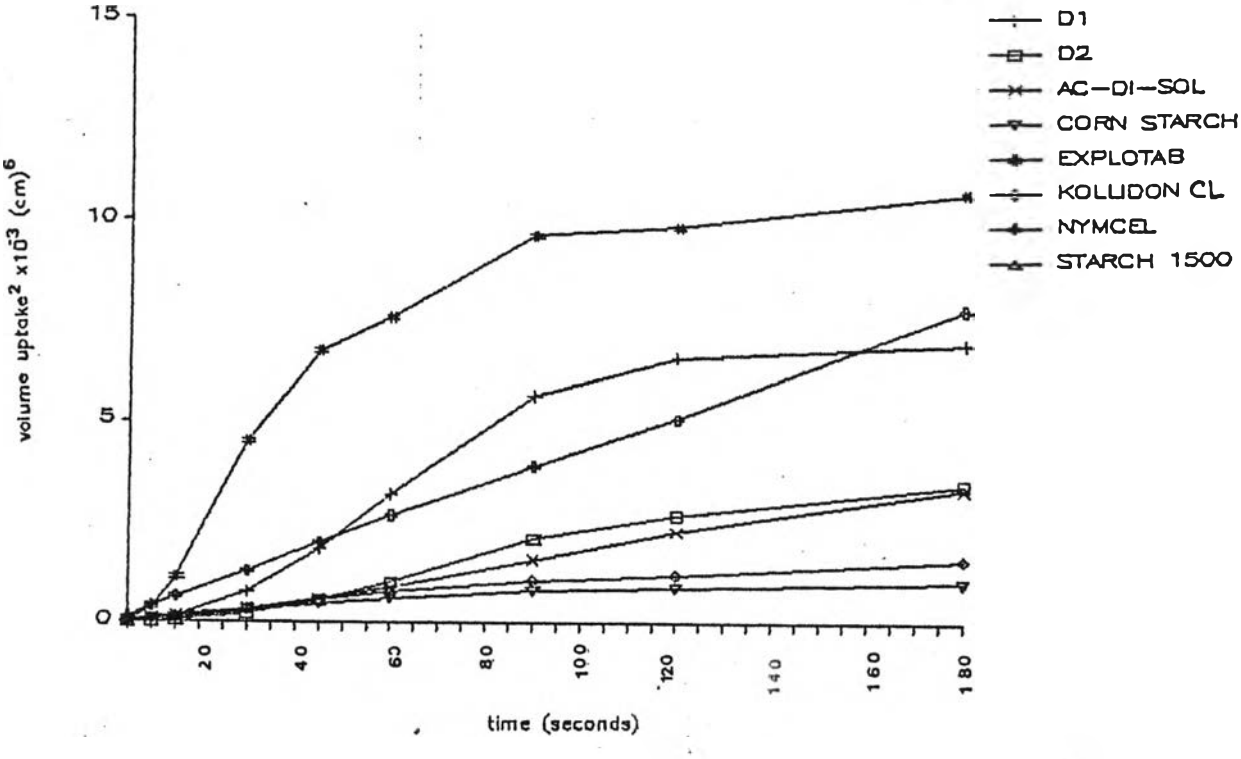


Figure 42 Water penetration curve of various disintegrants at 1% concentration in ∝-lactose monohydrate tablets, compressed at 500 kg.

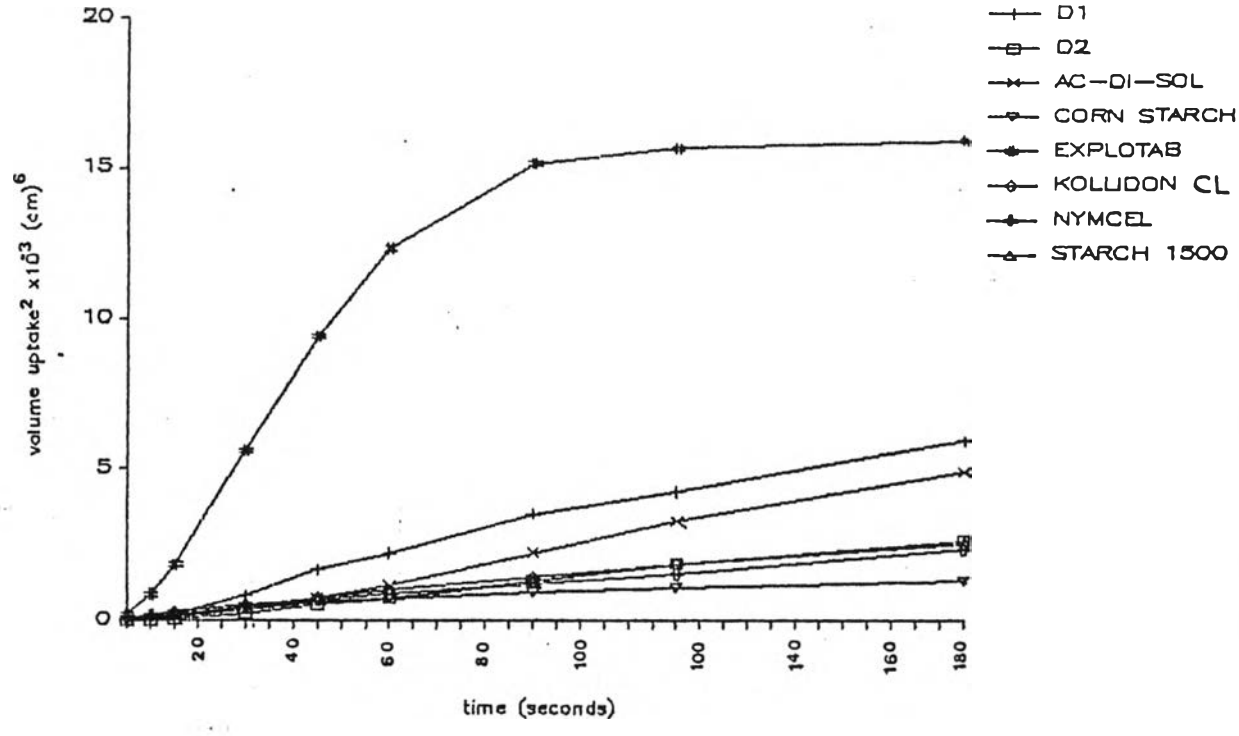


Figure 43 Water penetration curve of various disintegrants at 2 % concentration in ∝-lactose monohydrate tablets, compressed at 500 kg.

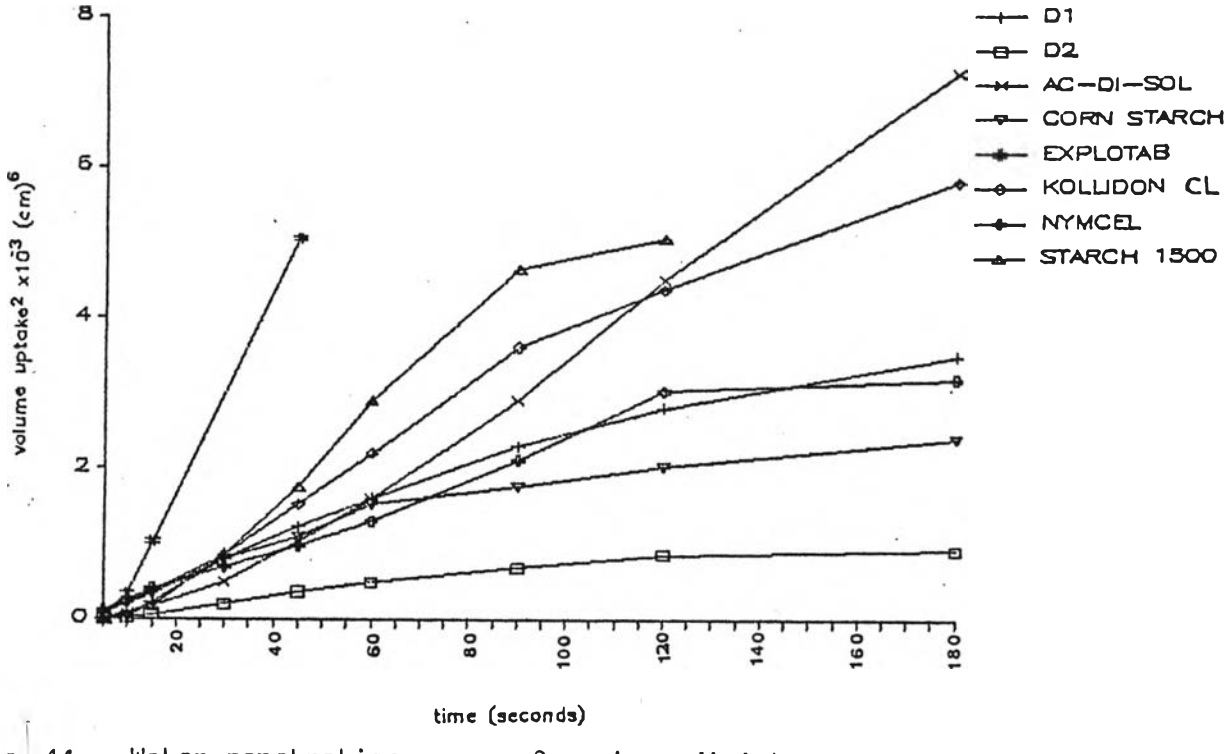


Figure 44 Water penetration curve of various disintegrants at 5% concentration in ∝-lactose monohydrate tablets, compressed at 500 kg.

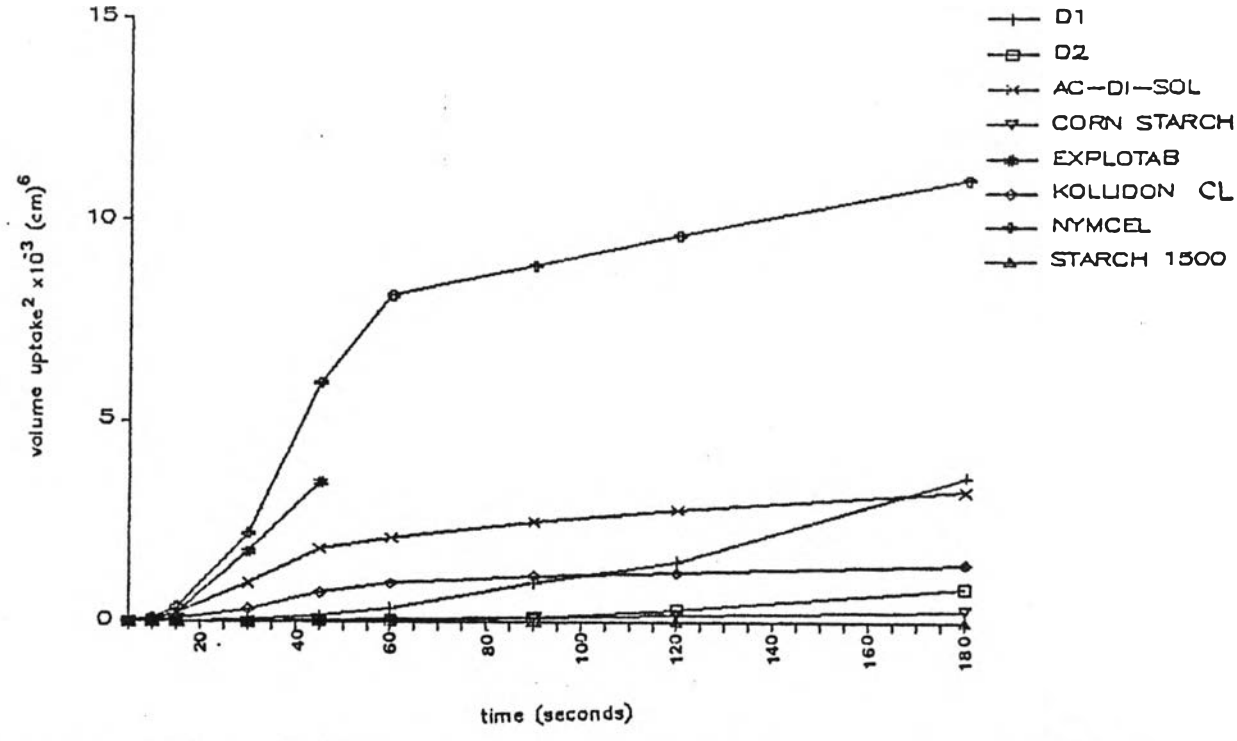


Figure 45 Water penetration curve of various disintegrants at 0.5% concentration in ∝-lactose monohydrate tablets, compressed at 1000 kg.

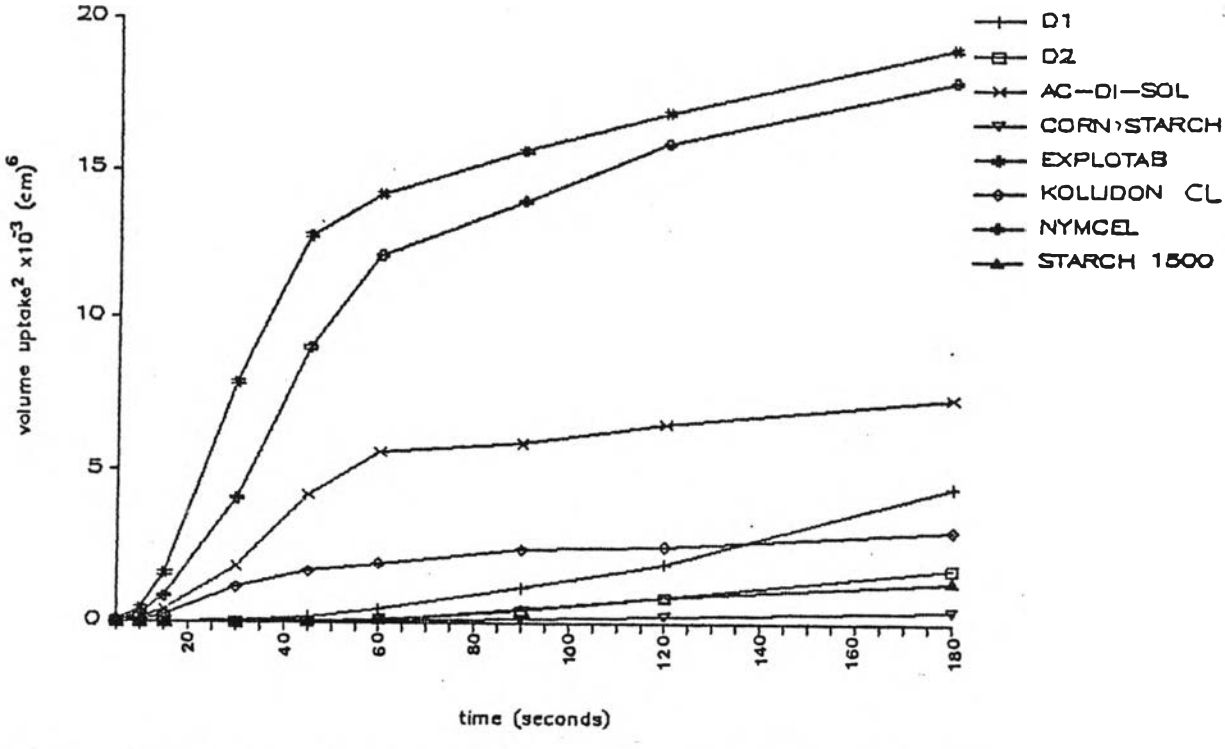


Figure 46 Water penetration curve of various disintegrants at 1% concentration in ∝-lactose monohydrate tablets, compressed at 1000 kg.

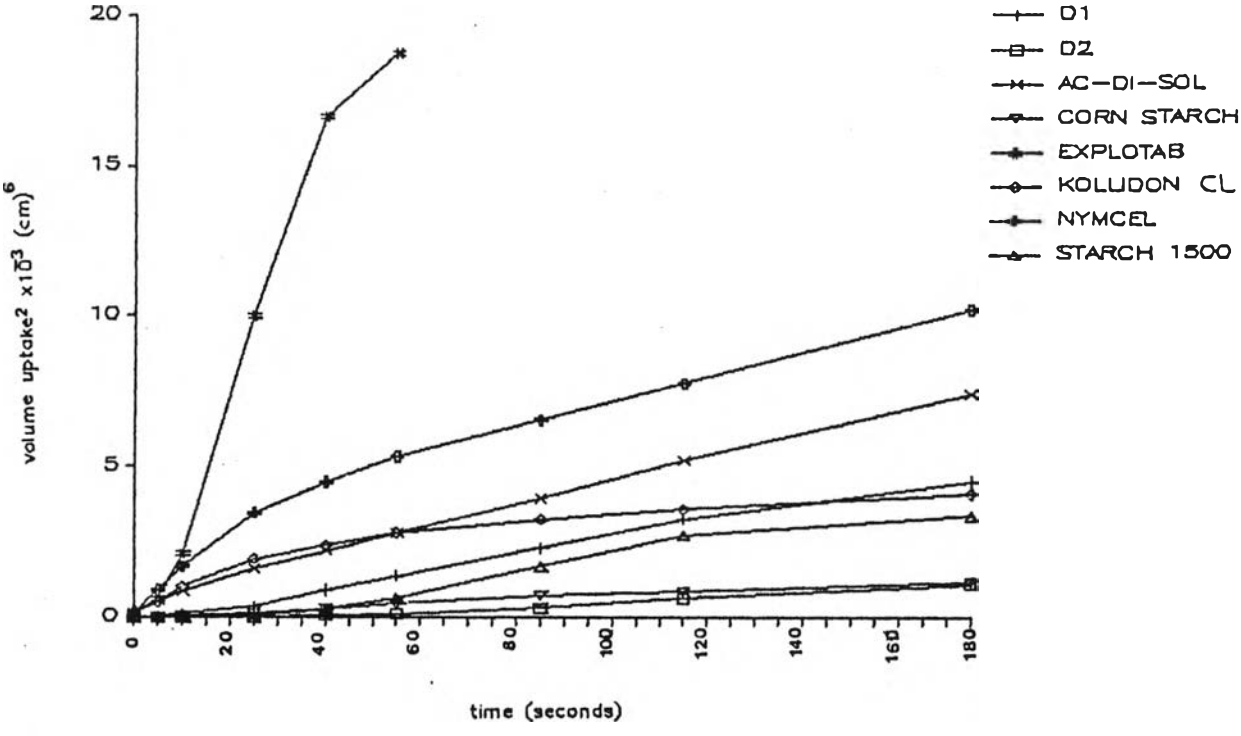


Figure 47 Water penetration curve of various disintegrants at 2% concentration in ∝-lactose monohydrate tablets, compressed at 1000 kg.

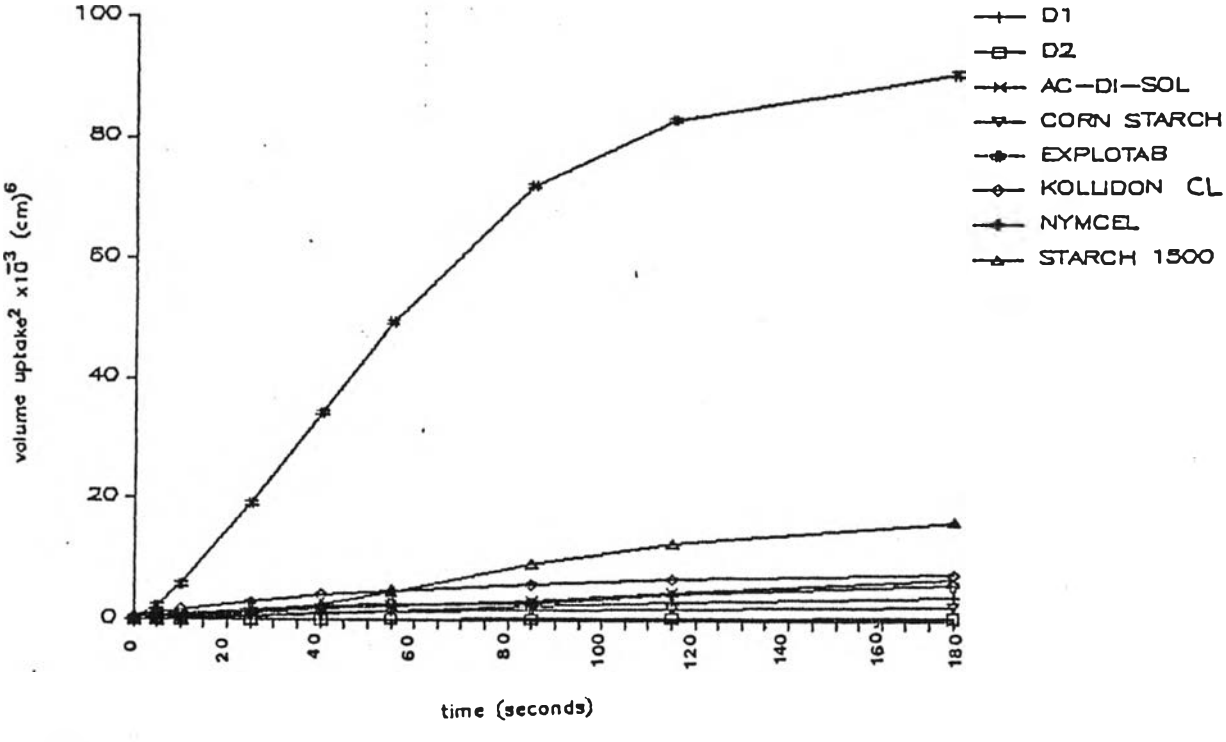


Figure 48 Water penetration curve of various disintegrants at 5% concentration in ∝-lactose monohydrate tablets, compressed at 1000 kg.

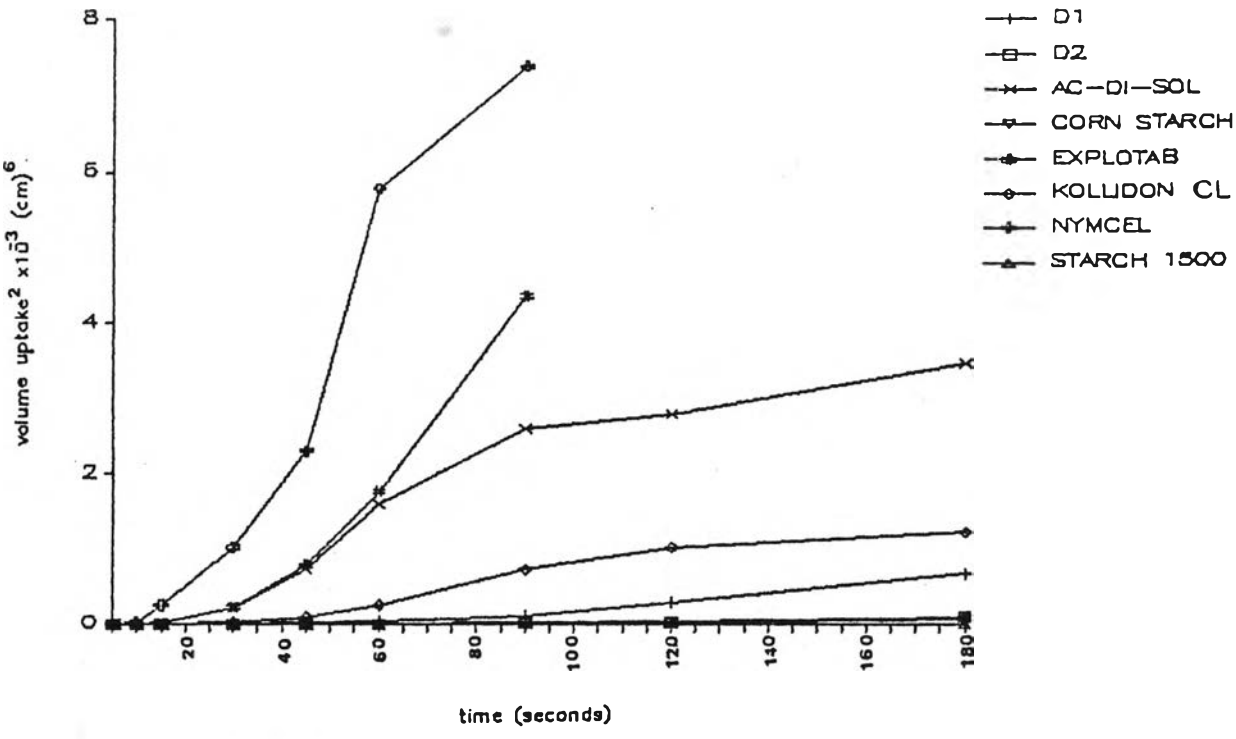


Figure 49 Water penetration curve of various disintegrants at 0.5% concentration in ∝-lactose monohydrate tablets, compressed at 1500 kg.

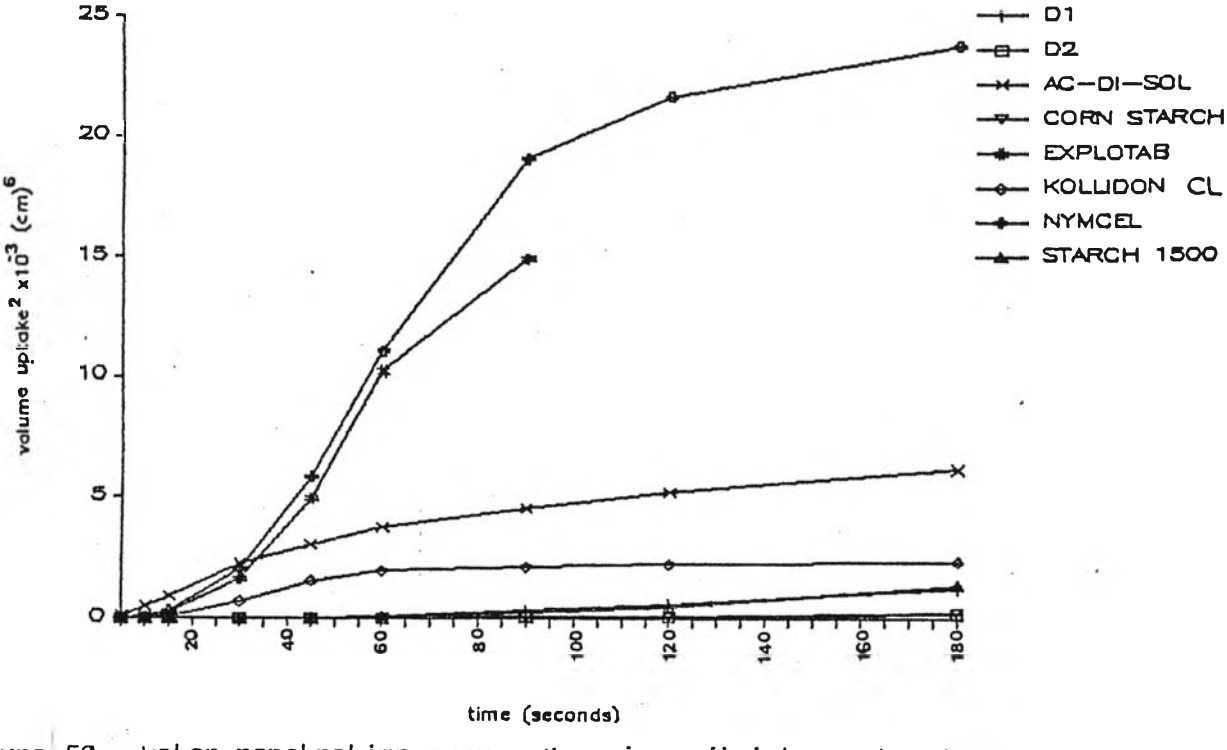


Figure 50 water penetration curve of various disintegrants at 1% concentration in ∝-lactose monohydrate tablets, compressed at 1500 kg.

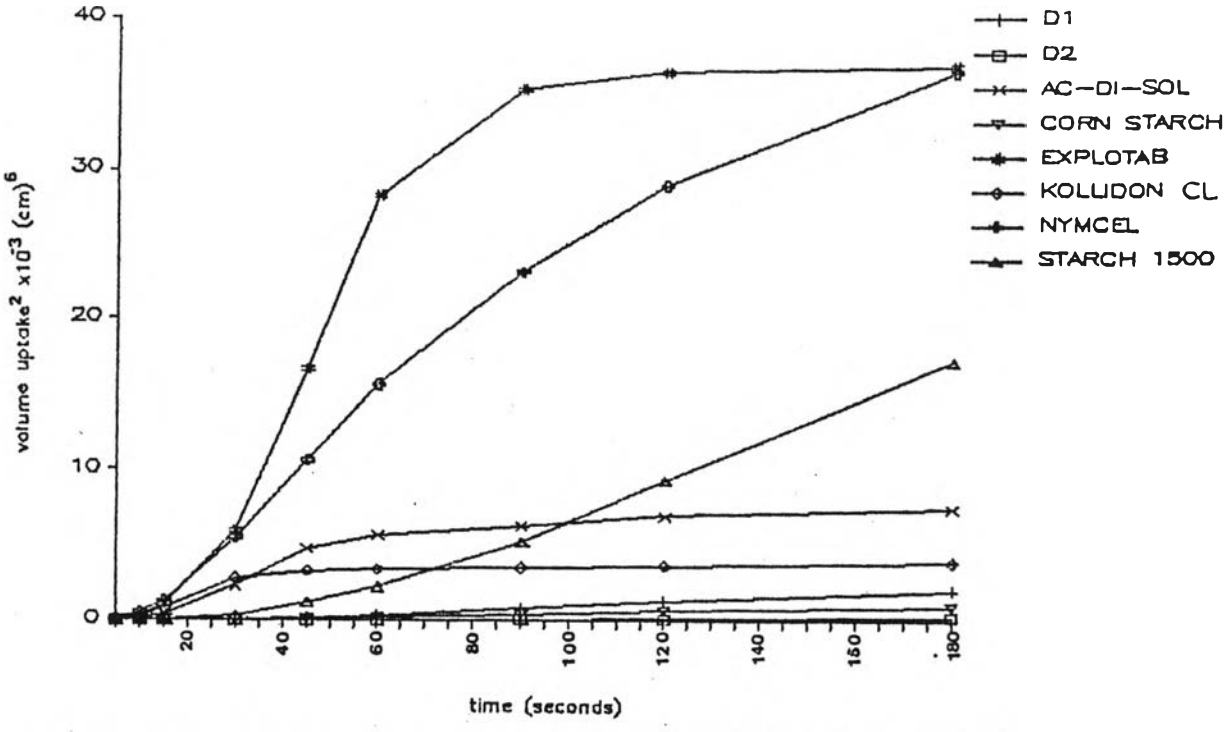


Figure 51 Water penetration curve of various disintegrants at 2% concentration in ∝-lactose monohydrate tablets, compressed at 1500 kg.

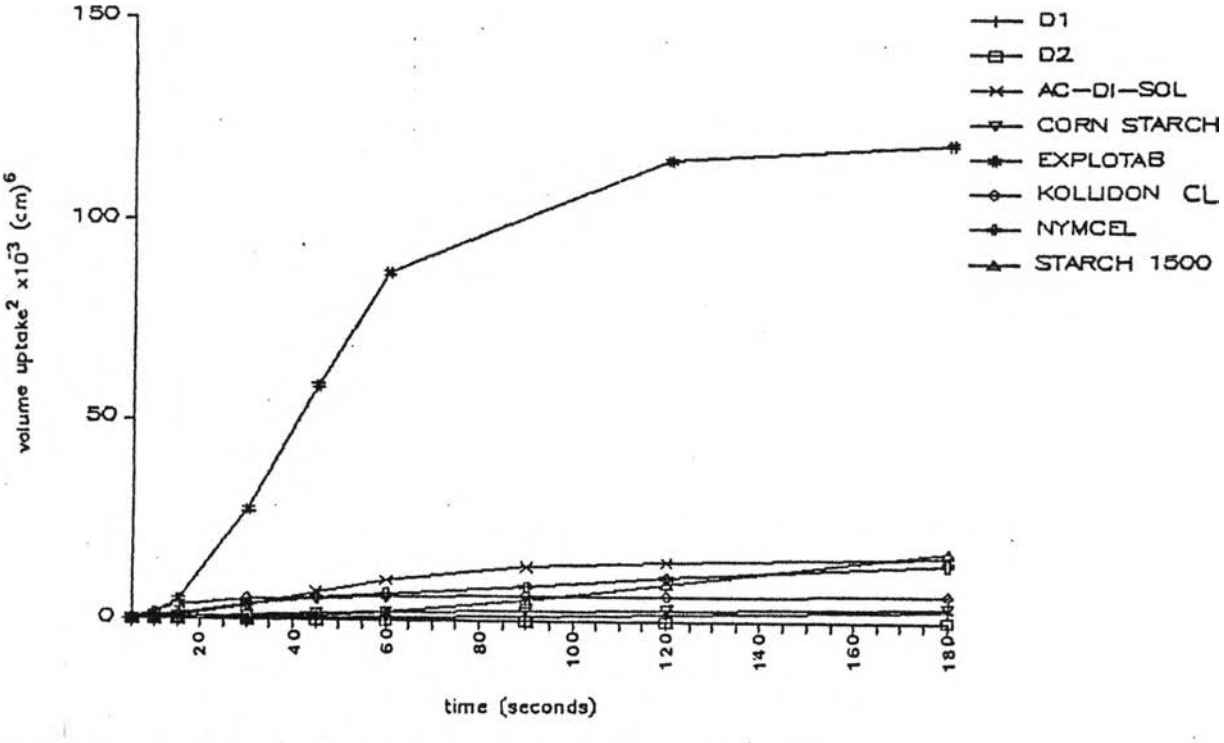


Figure 52 Water penetration curve of various disintegrants at 5% concentration in ∝-lactose monohydrate tablets, compressed at 1500 kg.

Table 26

The Rank of Efficiency of Various Disintegrants in Dibasic Calcium Phosphate Dihydrate Tablets at Different Concentrations and Compressional Forces on the Initial Rate of Water Penetration.

Force (Kg)	Concentration(%)	Disintegrant							
		D_1	D_2	Ac-di-Sol(R)	Corn starch	Explotab(R)	Kollidon CL(R)	Nymcel(R)	Starch 1500(R)
500	0.5	-	5	2	-	3	4	1	6
	1.0	4	5	3	-	1	7	2	6
	2.0	4	5	1	8	3	7	2	6
	5.0	5	6	2	8	1	4	3	7
1000	0.5	-	5	4	-	2	3	1	6
	1.0	5	6	2	-	3	4	1	7
	2.0	5	6	1	8	2	3	4	7
	5.0	5	6	4	7	2	1	3	8
1500	0.5	-	5	1	-	4	3	2	-
	1.0	5	6	1	-	2	3	4	-
	2.0	5	6	1	7	4	2	3	-
	5.0	5	6	2	7	4	1	3	8

- water penetration was not observed.

1 the best efficiency

Table 27

The Rank of Efficiency of Various Disintegrants in α-Lactose Monohydrate Tablets at Different Concentrations and Compressional Forces on the Initial Rate of Water Penetration.

Force (Kg) / Concentration(%)		Disintegrant							
		D_1	D_2	Ac-di-Sol®	Corn starch	Explotab®	Kollidon CL®	Nymcel®	Starch 1500®
500	0.5	6	7	3	4	1	5	2	8
	1.0	5	7	3	4	2	6	1	8
	2.0	5	7	1	8	3	4	2	6
	5.0	5	7	1	6	2	3	4	8
1000	0.5	5	7	2	6	3	4	1	-
	1.0	6	8	2	5	1	4	3	7
	2.0	6	8	2	5	4	3	1	7
	5.0	7	8	4	5	2	1	3	6
1500	0.5	5	7	3	6	2	4	1	-
	1.0	5	8	1	7	3	4	2	6
	2.0	6	8	4	5	2	3	1	7
	5.0	7	8	4	5	2	1	3	6

- water penetration was not observed.

1 the best efficiency

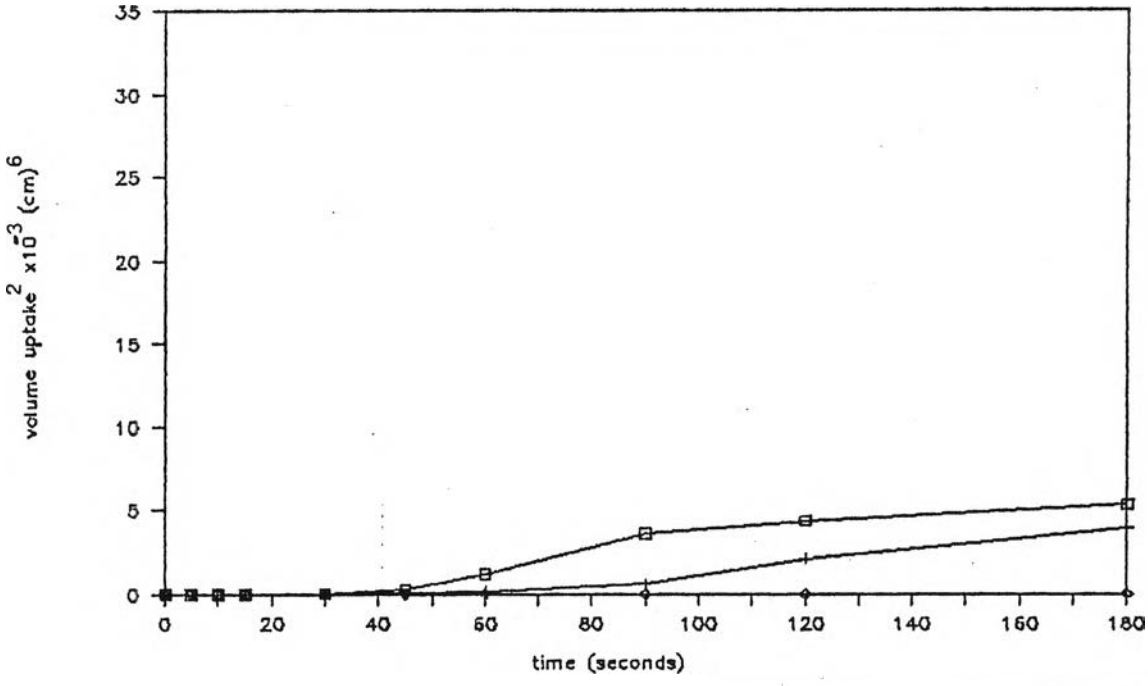


Figure 53 Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing D_1 at 1% concentration as a function of time.
□ 500 kg, + 1000 kg, ◊ 1500 kg.

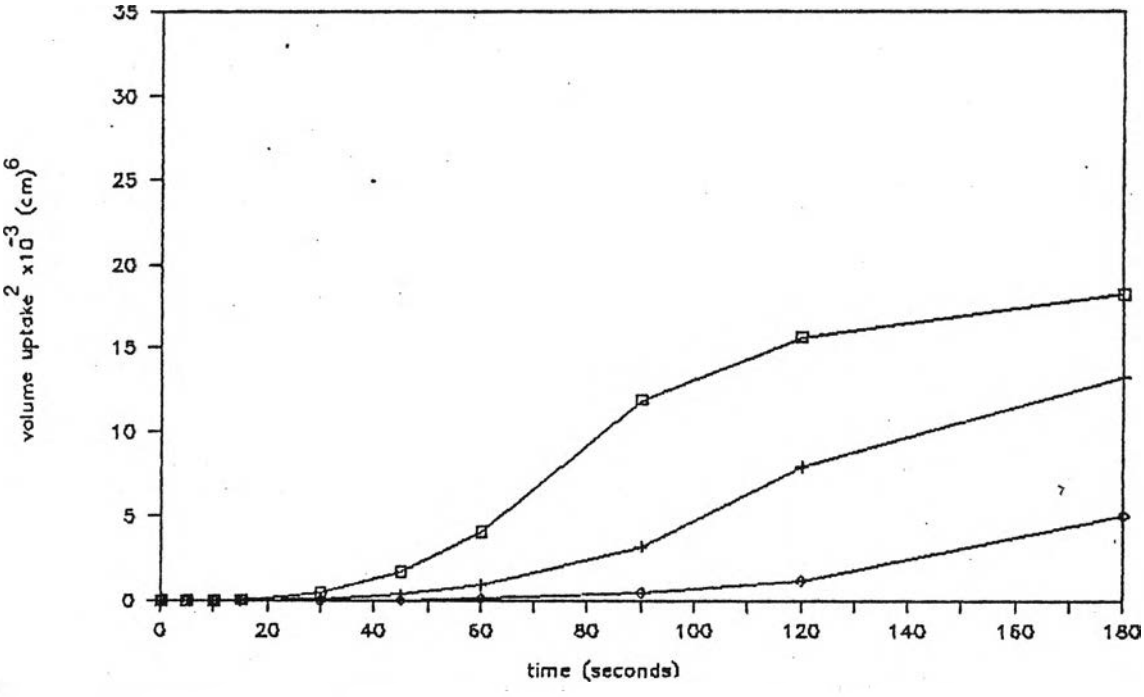


Figure 54 Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing D_1 at 2% concentration as a function of time.
□ 500 kg, + 1000 kg, ◊ 1500 kg.

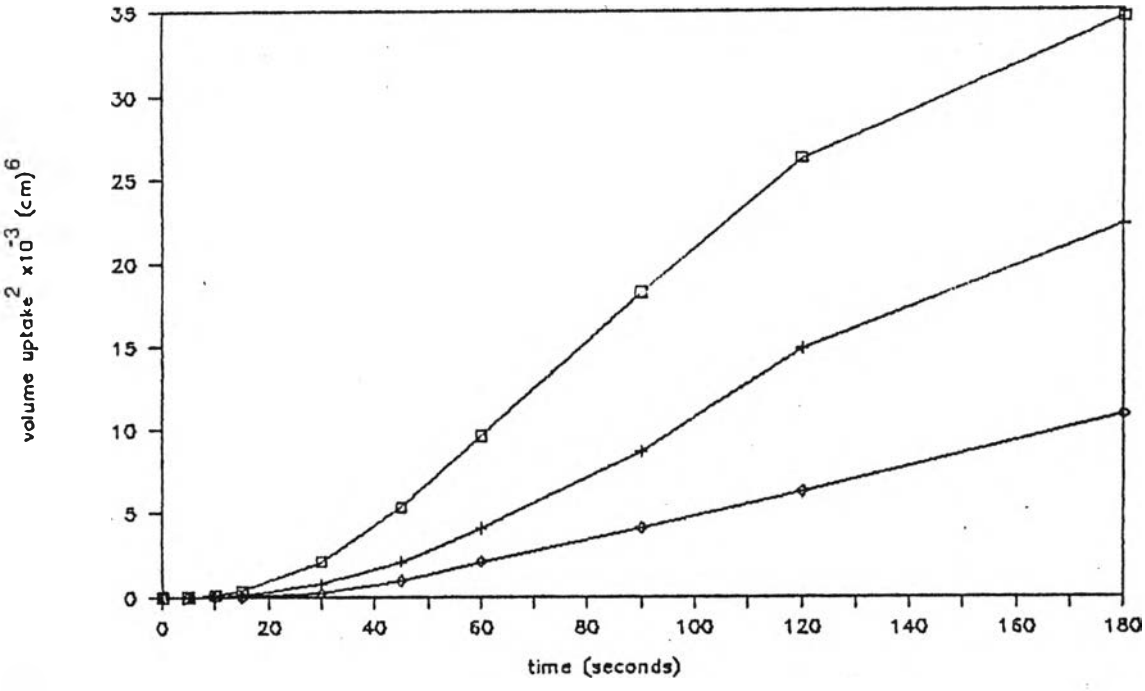


Figure 55 Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing D_1 at 5% concentration as a function of time.
▫ 500 kg, + 1000 kg, ◊ 1500 kg.

dibasic calcium phosphate dihydrate system, that was an increased in compressional force produced decreasing in water penetration as shown in Figures 56-59. But, when the amount of D_1 increased, the rate and extent of water uptake was slightly altered. However, at 5% level, the different on rate and extent of water uptake at three compressional forces became smaller than at lower concentrations. In addition, the lag time of penetration curve still increased as increasing compressional force or decreasing concentration of D_1

2. D_2

2.1 Water insoluble diluent

The water penetration into directly compressed dibasic calcium phosphate dihydrate tablets containing D_2 at three compressional forces are demonstrated in Figures 60-63. As the same as in D_1 system increase in compressional force resulted in decreasing rate of water penetration and increasing lag time (except for D_2 5%, at 1500 kg the penetration was greater than at 1000 kg). Water penetration was also markedly increased when increase amount of D_2.

2.2 Water soluble diluent

The effect of D_2 upon water penetration of directly compressed α-lactose monohydrate system at three compressional forces are shown in Figures 64-67. These figures depicts the same behavior as water insoluble system in the influence of compressional forces on water uptake. However, increase in concentration of D_2 caused water uptake change in different way from water insoluble system. On increasing D_2 concentration the rate and extent of water uptake had tendency to increase until at 2% level the reverse effect started to

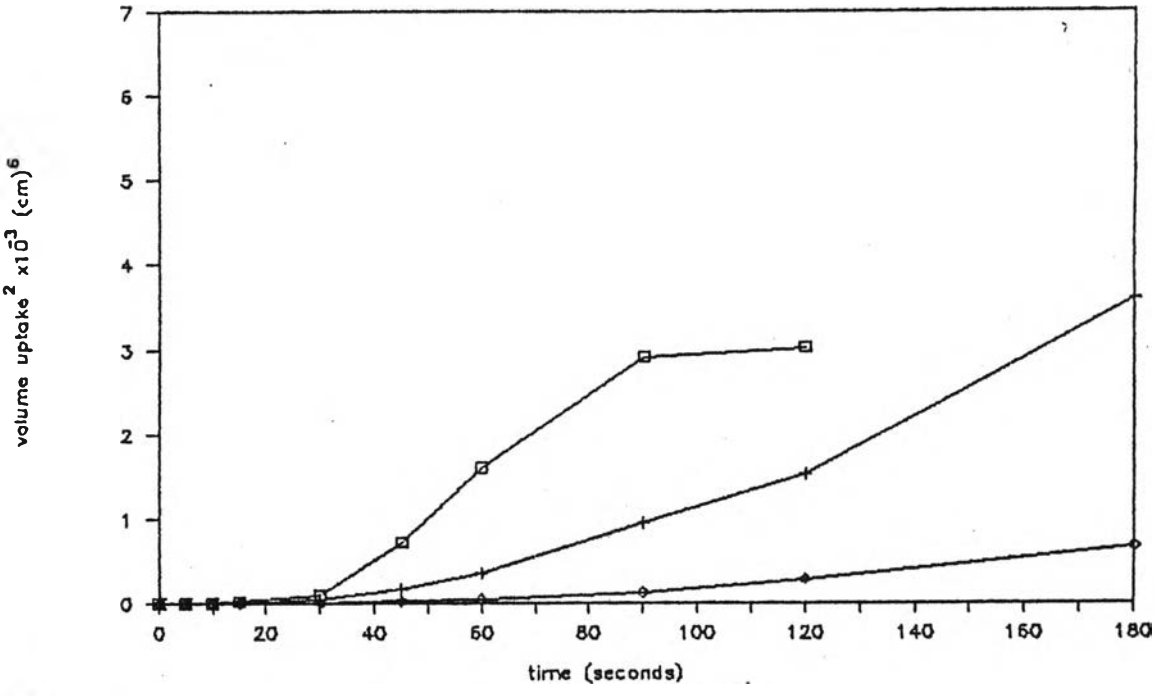


Figure 56 Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing D_1 at 0.5% concentration as a function of time. □ 500 kg, + 1000 kg, ◇ 1500 kg.

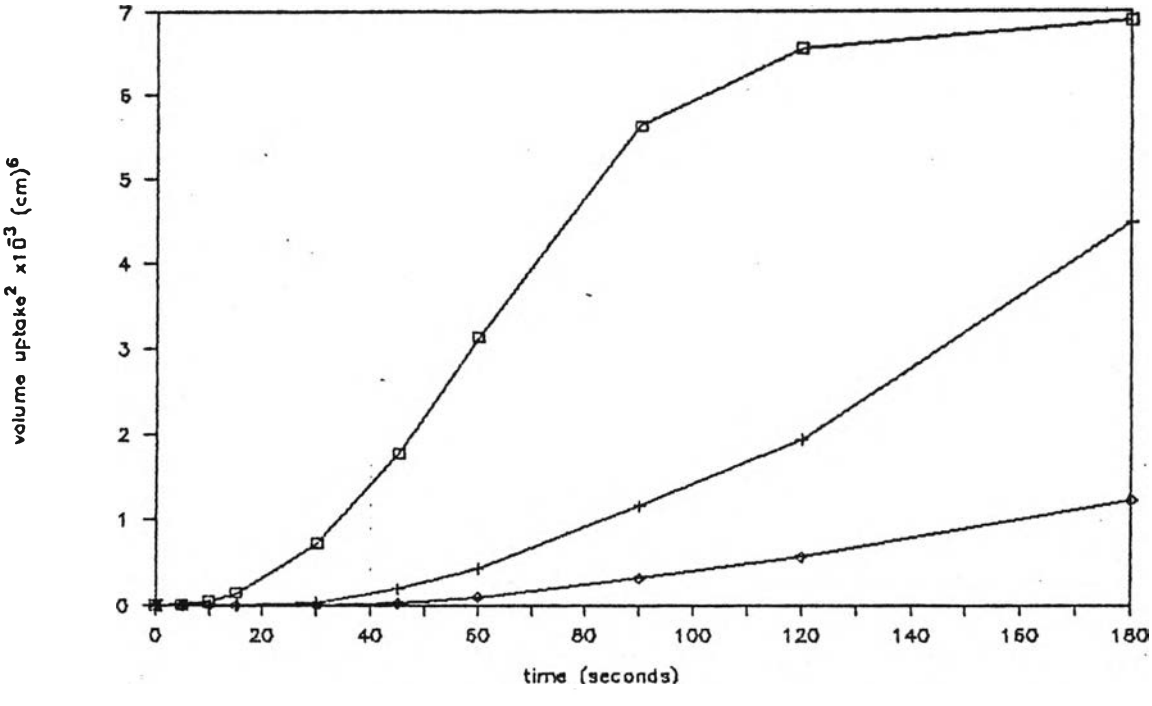


Figure 57 Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing D_1 at 1% concentration as a function of time. □ 500 kg, + 1000 kg, ◇ 1500 kg.

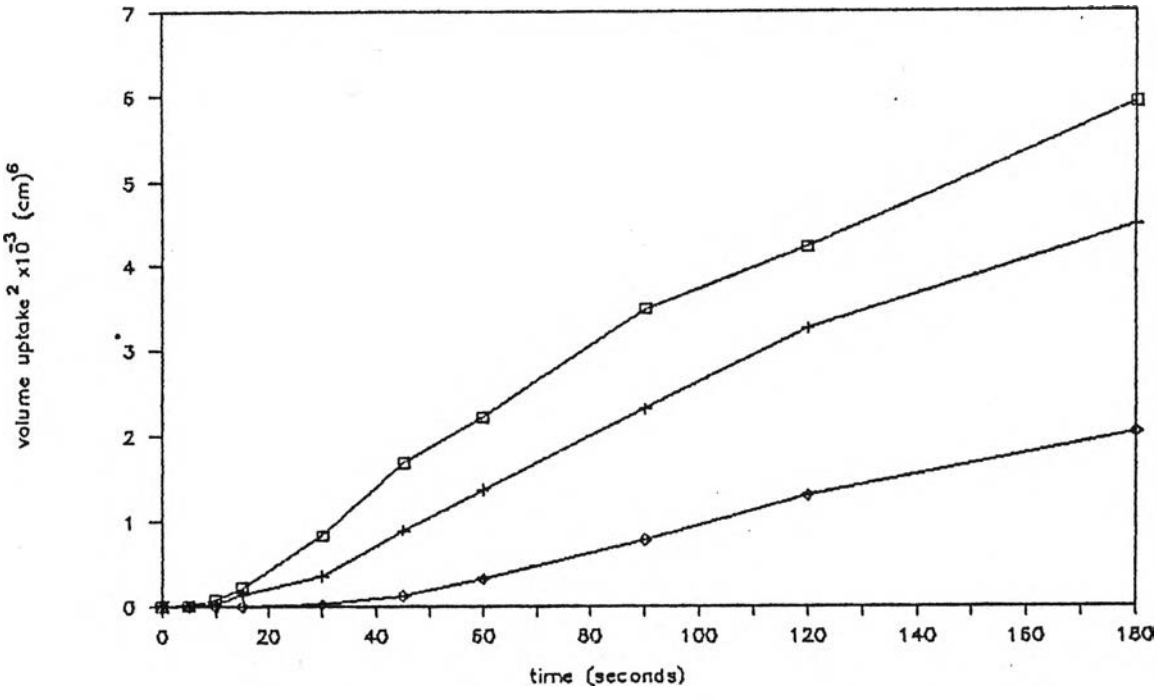


Figure 58 Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing D_1 at 2% concentration as a function of time. □ 500 kg, + 1000 kg, ◊ 1500 kg.

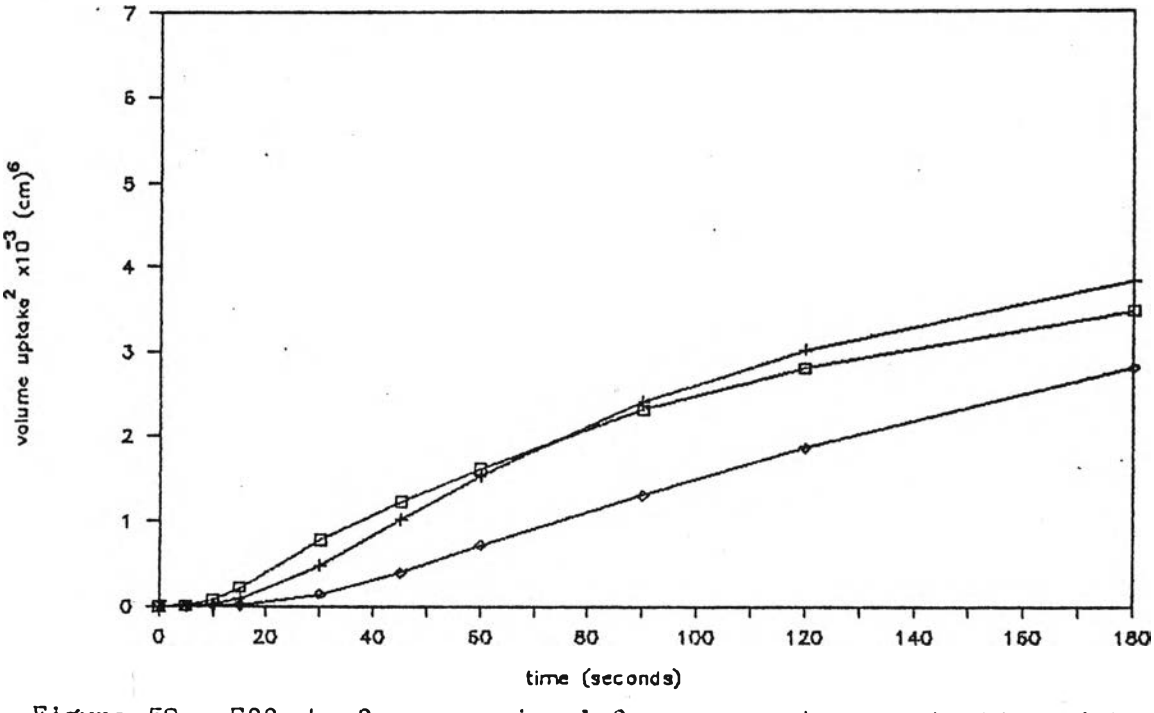


Figure 59 Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing D_1 at 5% concentration as a function of time. □ 500 kg, + 1000 kg, ◊ 1500 kg.

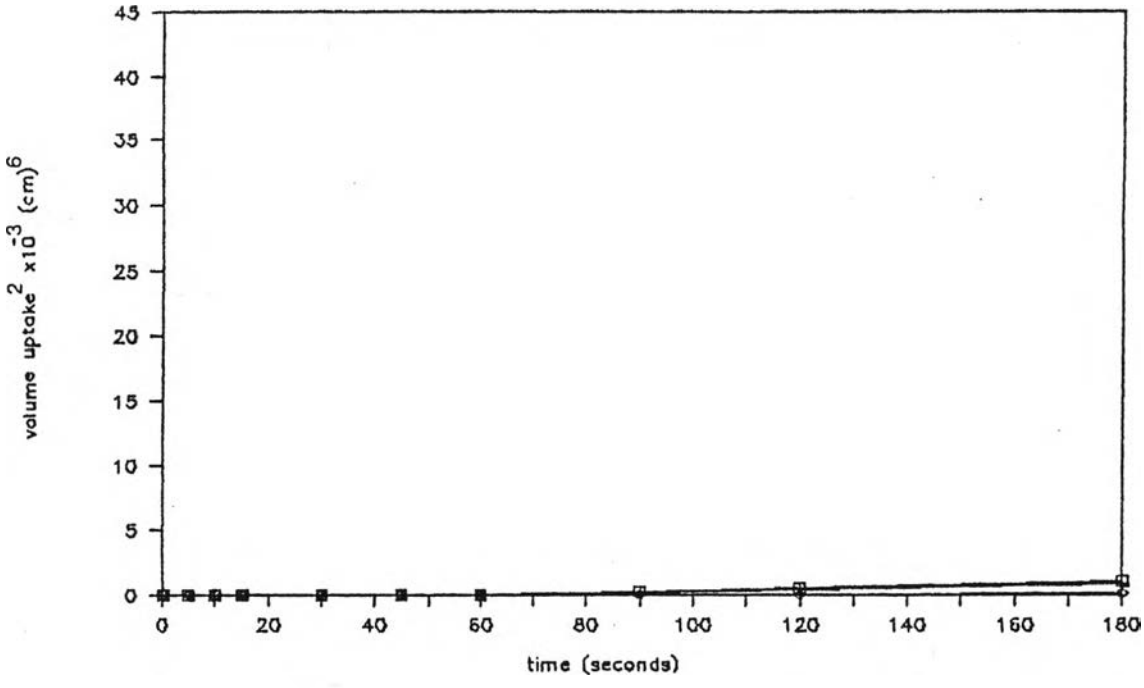


Figure 60 Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing D_2 at 0.5% concentration as a function of time.
□ 500 kg, + 1000 kg, ◊ 1500 kg.

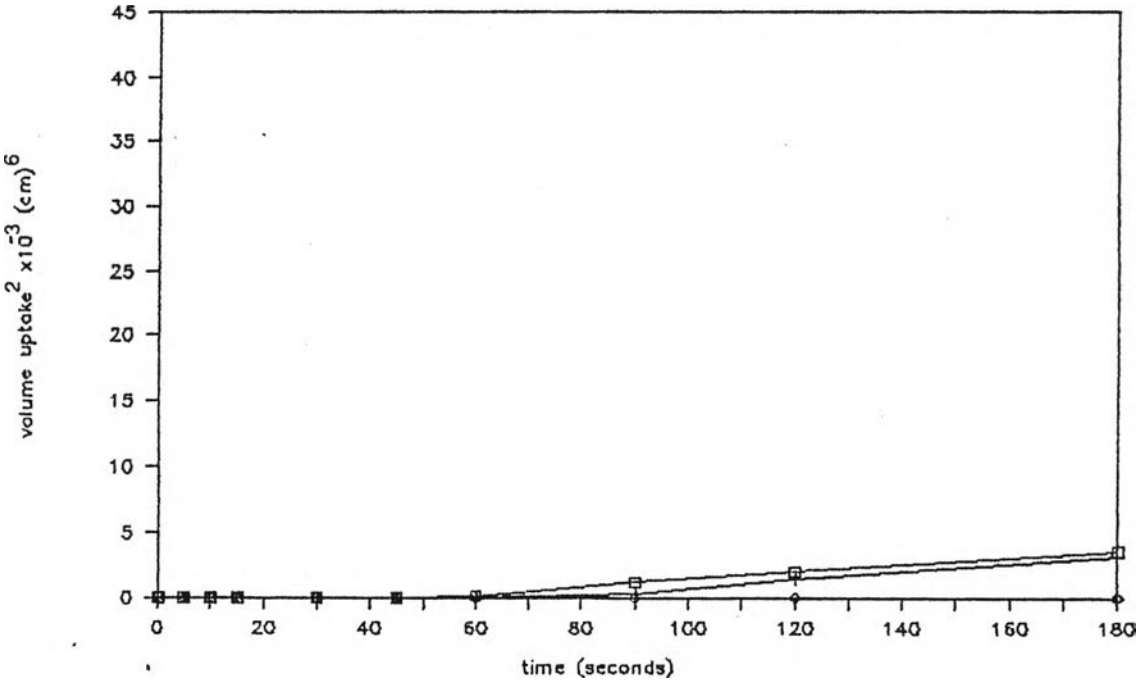


Figure 61 Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing D_2 at 1% concentration as a function of time.
□ 500 kg, + 1000 kg, ◊ 1500 kg.

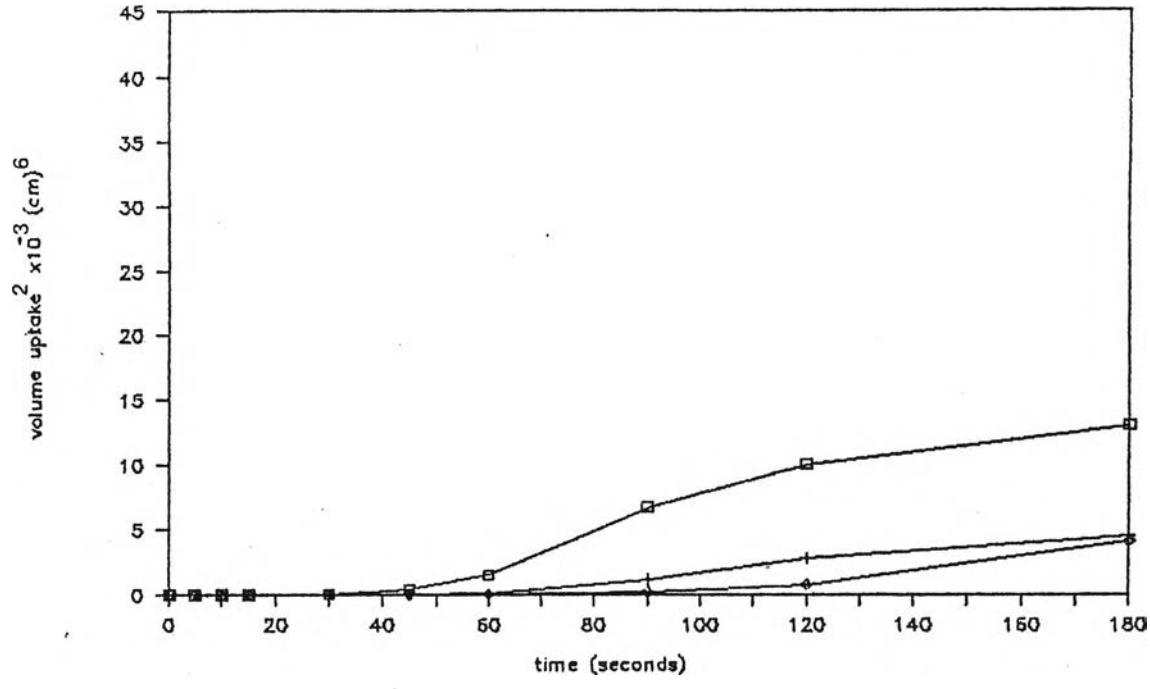


Figure 62 Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing D_2 at 2% concentration as a function of time.
□ 500 kg, + 1000 kg, ◊ 1500 kg.

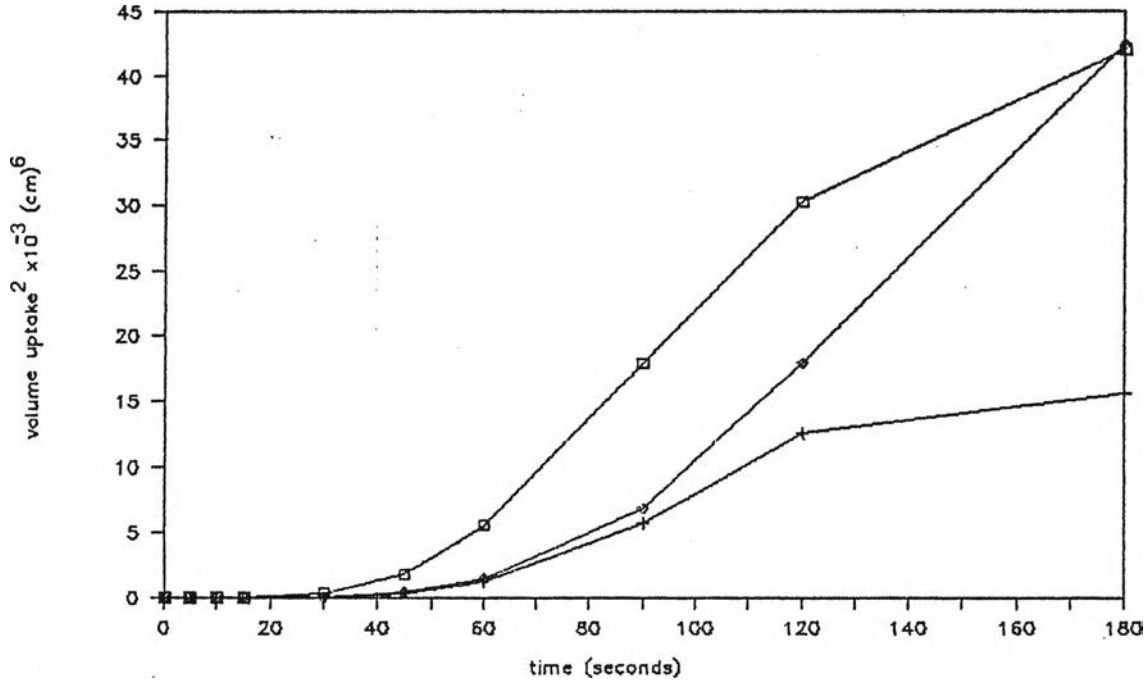


Figure 63 Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing D_2 at 5% concentration as a function of time.
□ 500 kg, + 1000 kg, ◊ 1500 kg.

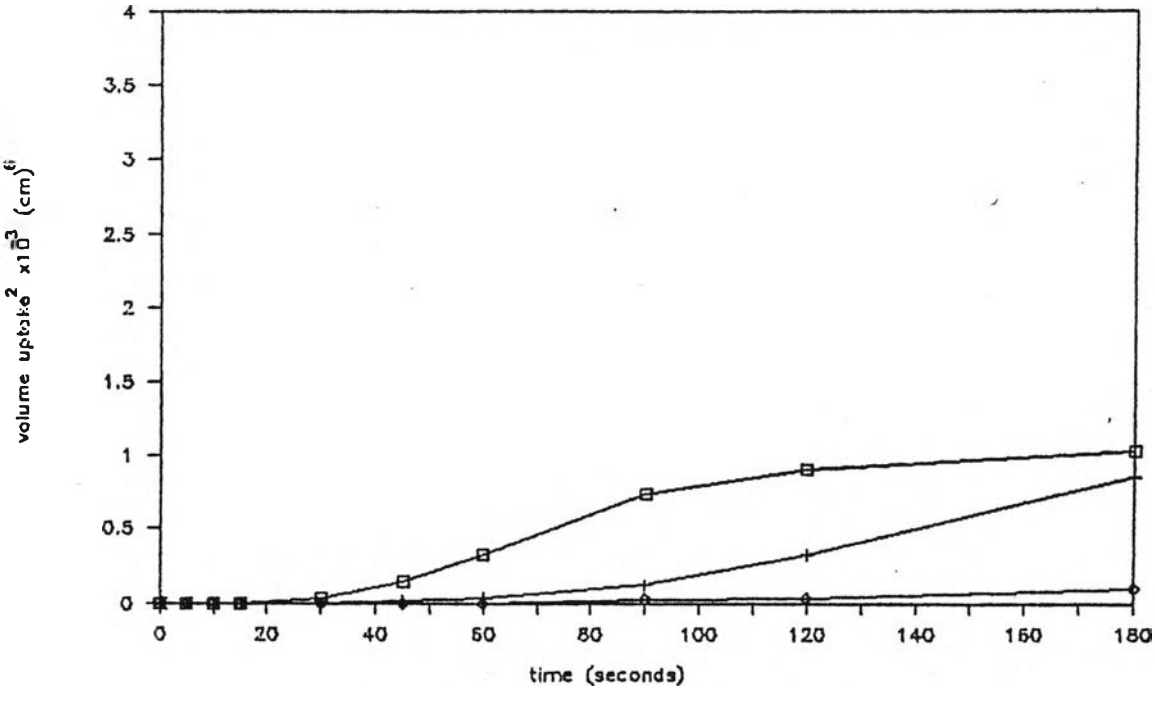


Figure 64 Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing D_2 at 0.5% concentration as a function of time. ▫ 500 kg, + 1000 kg, ◊ 1500 kg.

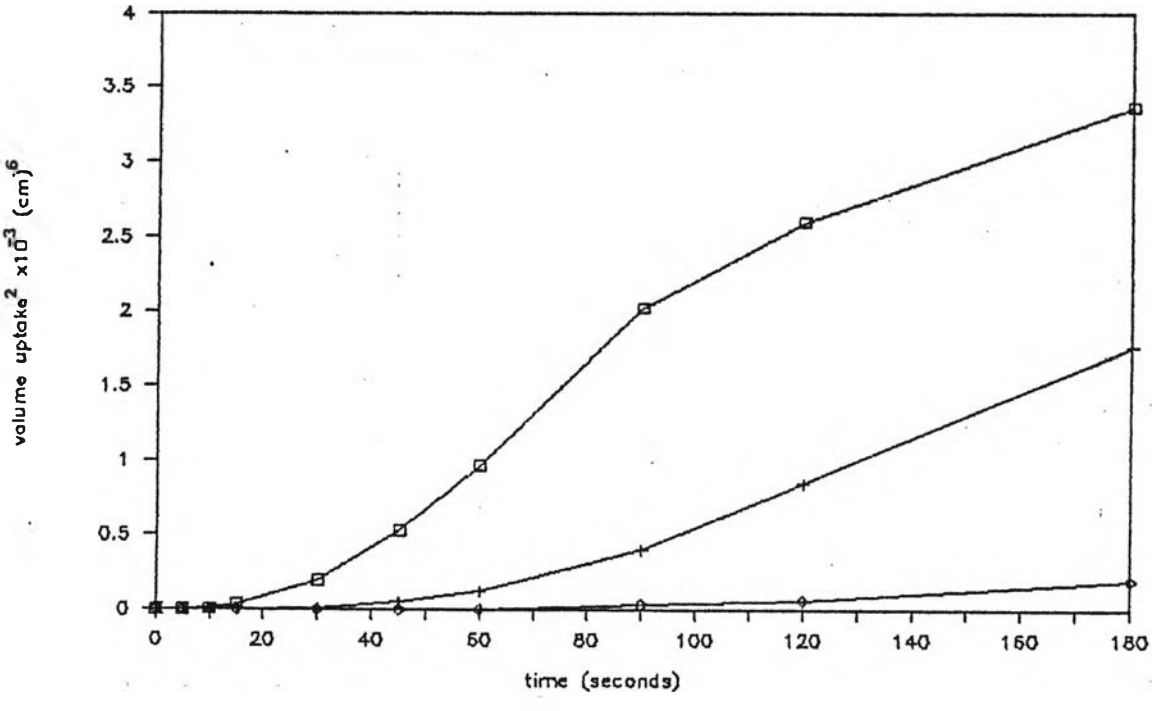


Figure 65 Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing D_2 at 1% concentration as a function of time. ▫ 500 kg, + 1000 kg, ◊ 1500 kg.

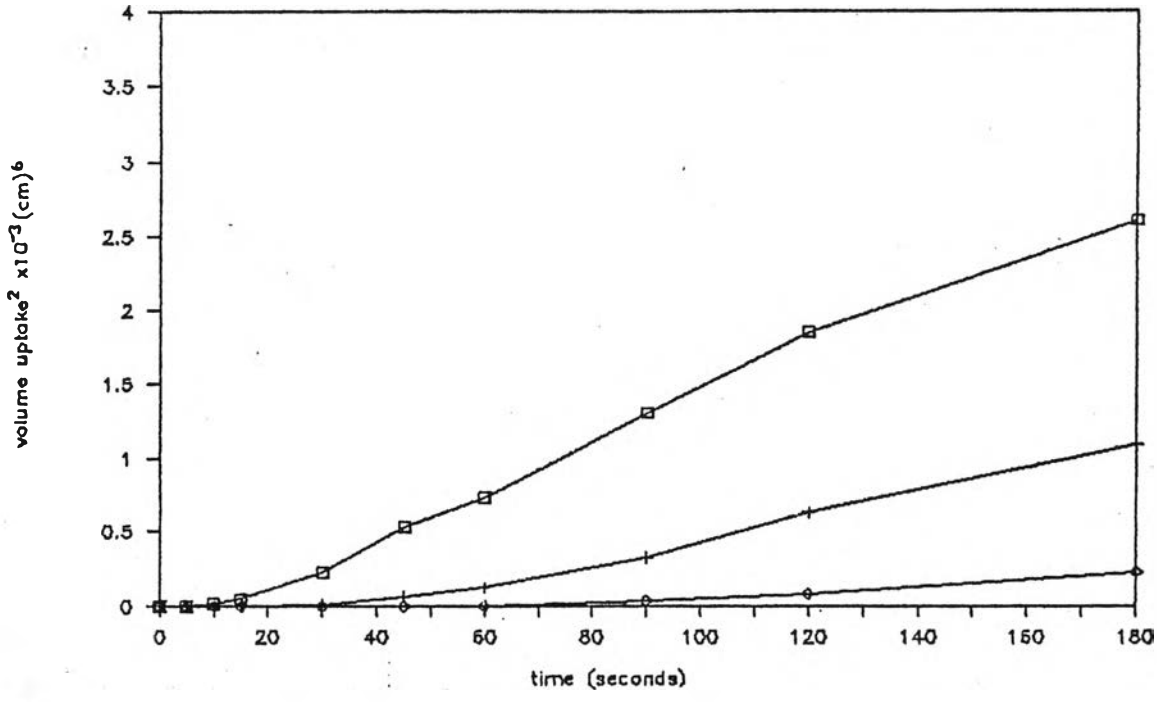


Figure 66 Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing D_2 at 2% concentration as a function of time. □ 500 kg, + 1000 kg, ◇ 1500 kg.

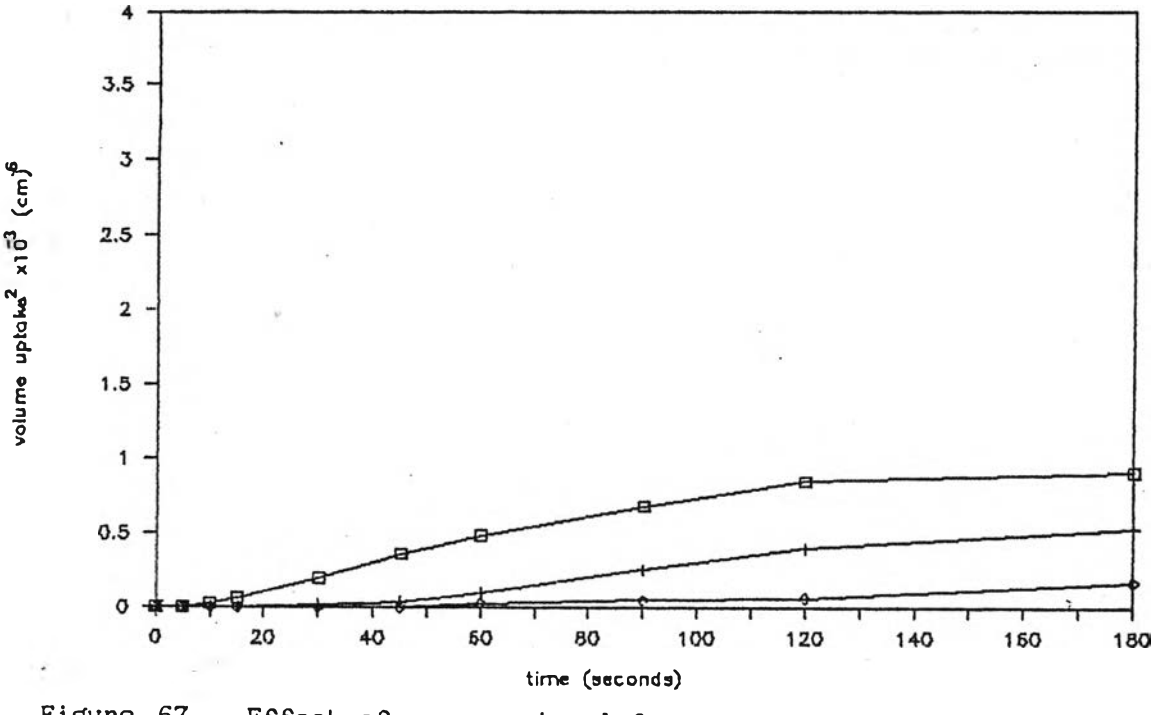


Figure 67 Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing D_2 at 5% concentration as a function of time. □ 500 kg, + 1000 kg, ◇ 1500 kg.

appedred. The tendency to decrease in the and exten were more pronounced at 5% level.

3. AC-DI-SOL(R)

3.1 Water insoluble diluent

Water penetration behaviors of tablets prepared from dibasic calcium phosphate dihydrate and Ac-di-Sol(R) are shown in Figures 68-71. Addition of Ac-di-Sol(R) obviously increased penetration rates and decreased lag time. On the other hand, increasing compressional force resulted in decreasing penetration rates. However, at the concentration of more than 1% the different in penetration rate at various compressional forces were slightly. Sometimes the greater the extent of water uptake at higher compressional force may presented than the lower ones.

3.2 Water soluble diluent

In the case of directly compressed α-lactose monohydrate system, compressional force exerted different influence on water penetration whereas water uptake tended to increase as compressional force increased as shown in Figures 72-75. The previously mentioned effect was obvious at the concentration of greater than 1%. At all of the compressional forces studied, the higher the concentration of Ac-di-Sol(R) the greater the rate of water uptake. However, the change in rate and extent of water penetration were small, as compared with water insoluble system.

4. Corn Starch

4.1 Water insoluble diluent

The water penetration into dibasic calcium phosphate dihydrate tablets containing corn starch when directly compressed at three compressional forces are demonstrated in

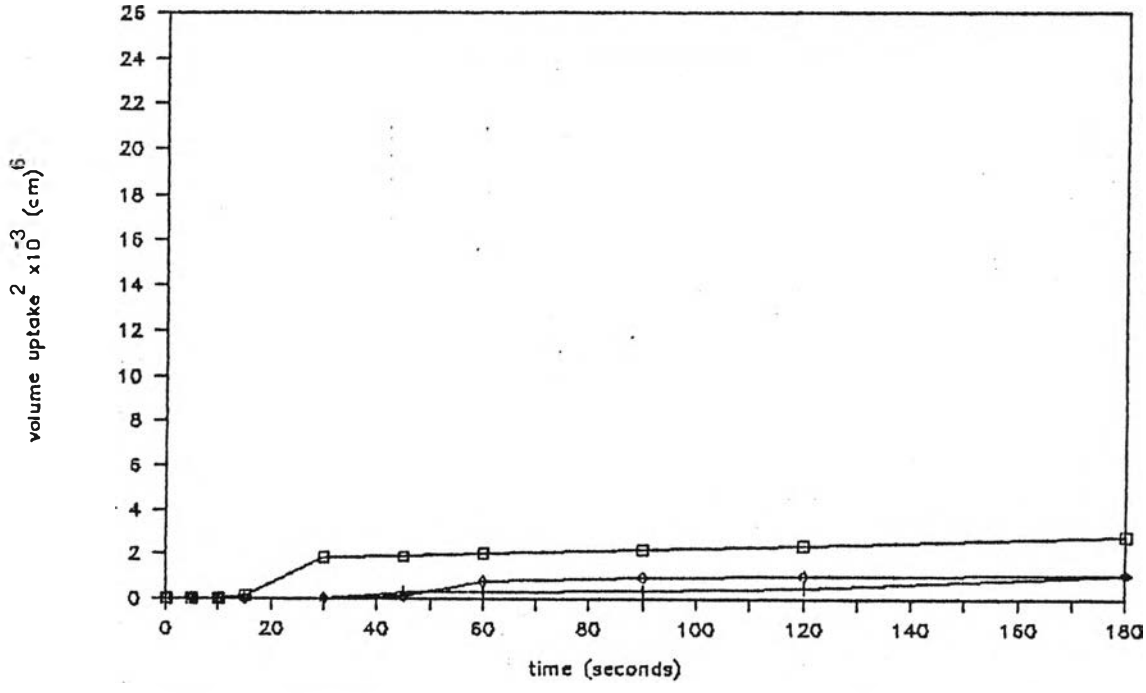


Figure 68 Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing Ac-di-Sol at 0.5% concentration as a function of time. ▫ 500 kg, + 1000 kg, ◊ 1500 kg.

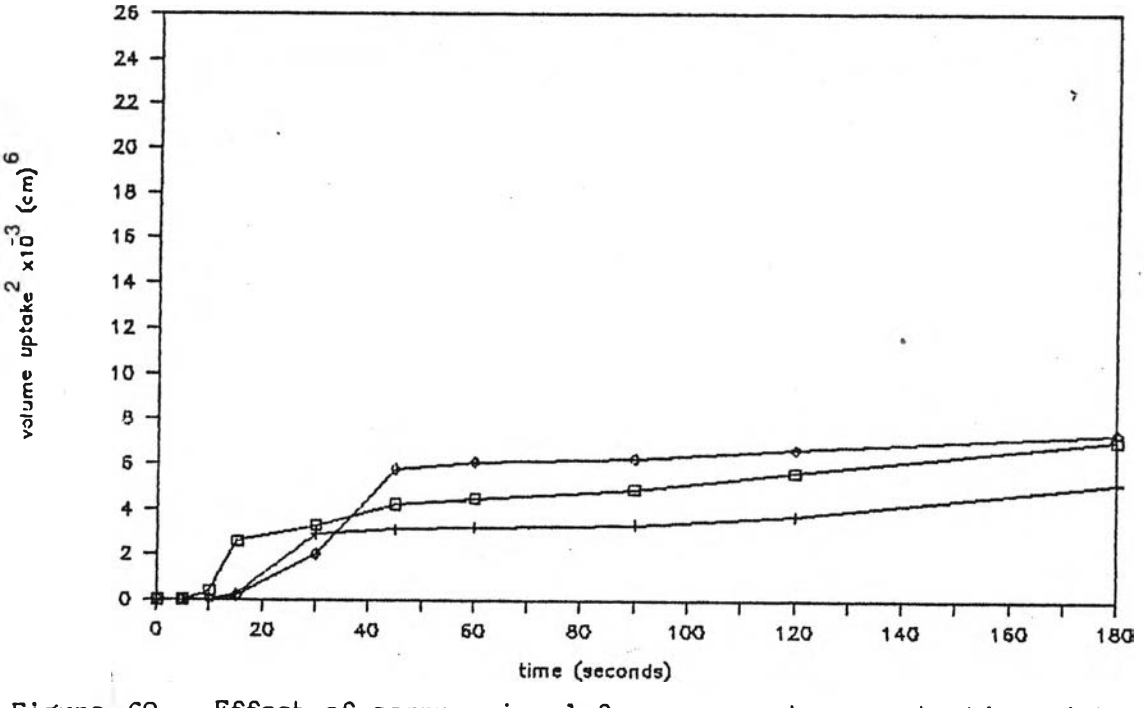


Figure 69 Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing Ac-di-Sol at 1% concentration as a function of time. ▫ 500 kg, + 1000 kg, ◊ 1500 kg.

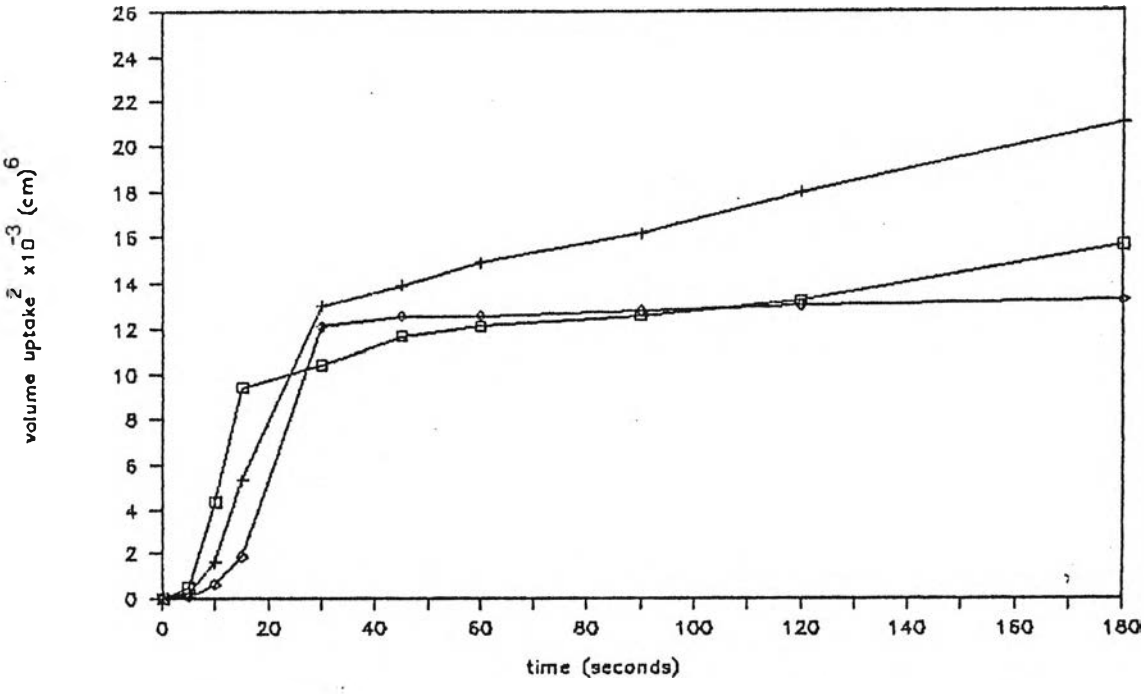


Figure 70 Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing Ac-di-Sol at 2% concentration as a function of time. ▫ 500 kg, + 1000kg, ◊ 1500 kg.

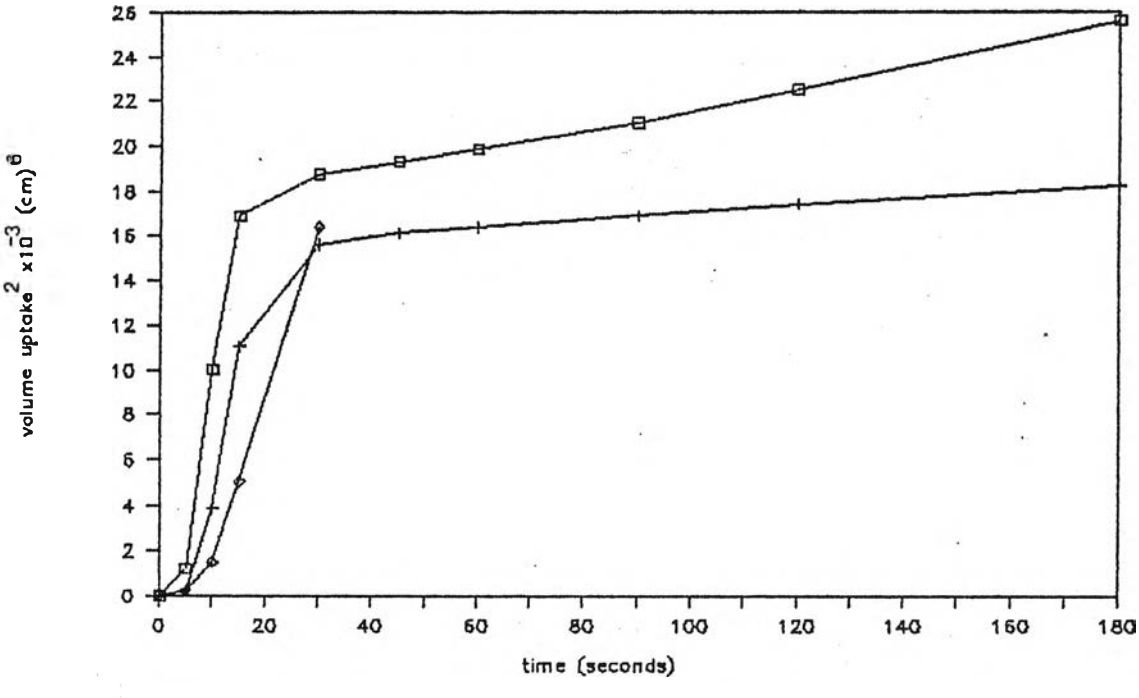


Figure 71 Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing Ac-di-Sol at 5% concentration as a function of time. ▫ 500 kg, + 1000kg, ◊ 1500 kg.

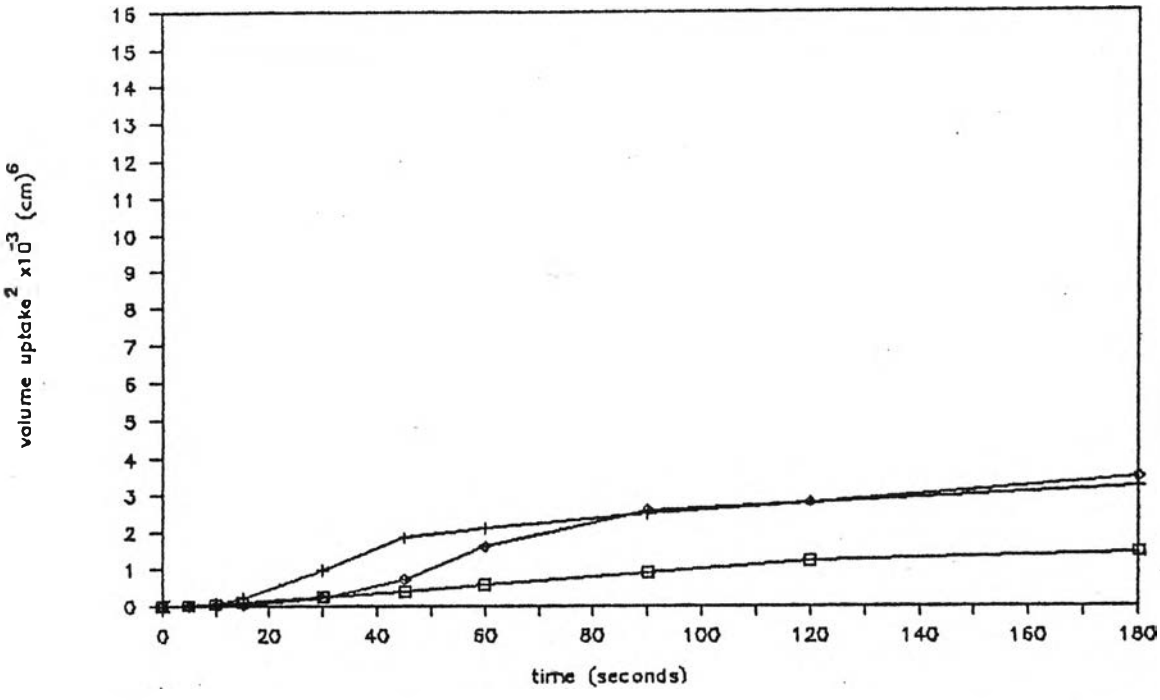


Figure 72 Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing Ac-di-Sol at 0.5% concentration as a function of time. ▫ 500 kg, + 1000 kg, ◊ 1500 kg.

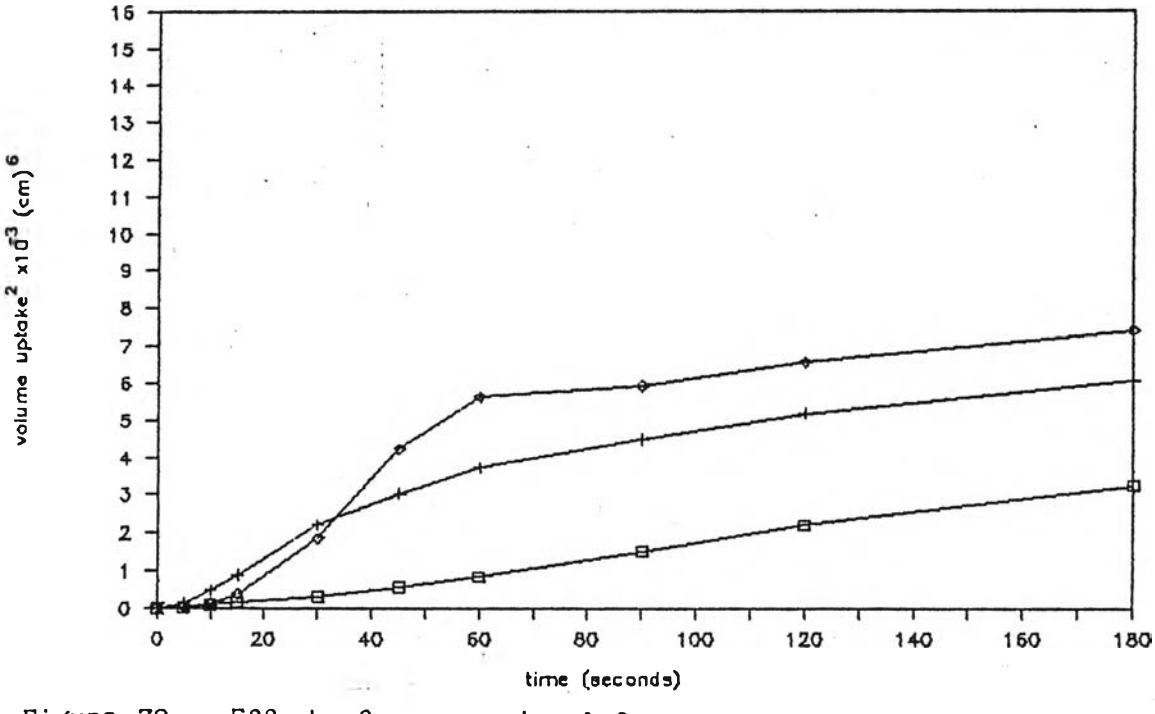


Figure 73 Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing Ac-di-Sol at 1% concentration as a function of time. ▫ 500 kg, + 1000 kg, ◊ 1500 kg.

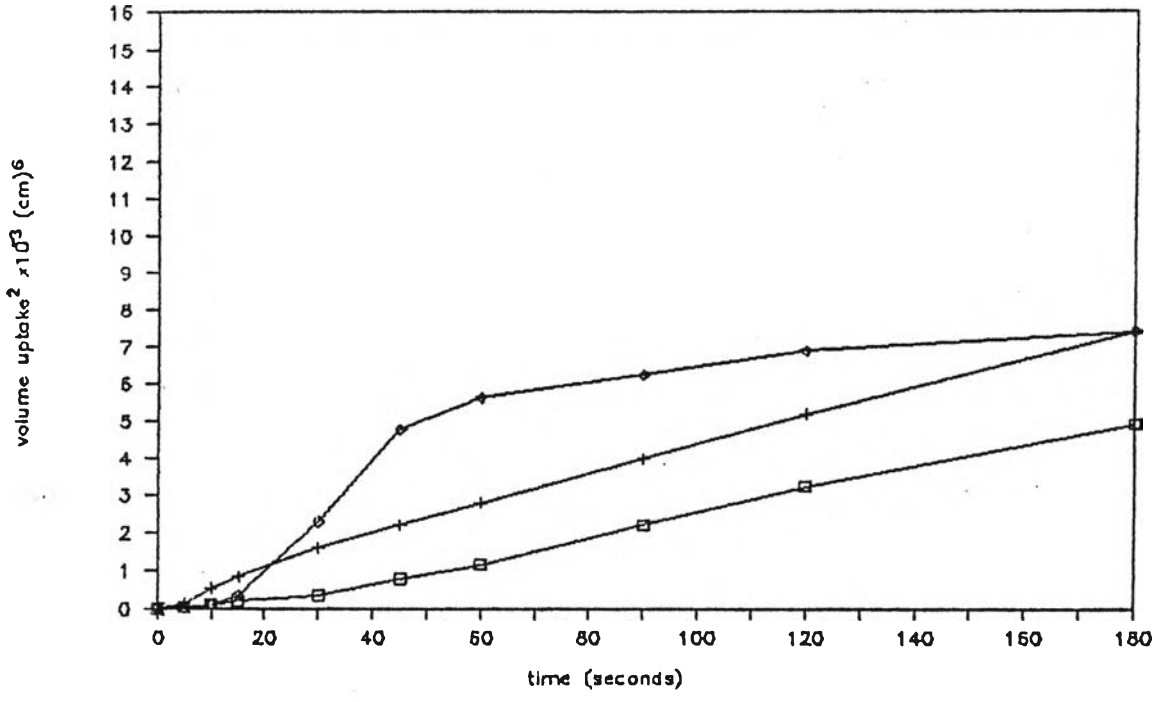


Figure 74 Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing Ac-di-Sol at 2% concentration as a function of time. □ 500 kg, + 1000 kg, ◊ 1500 kg.

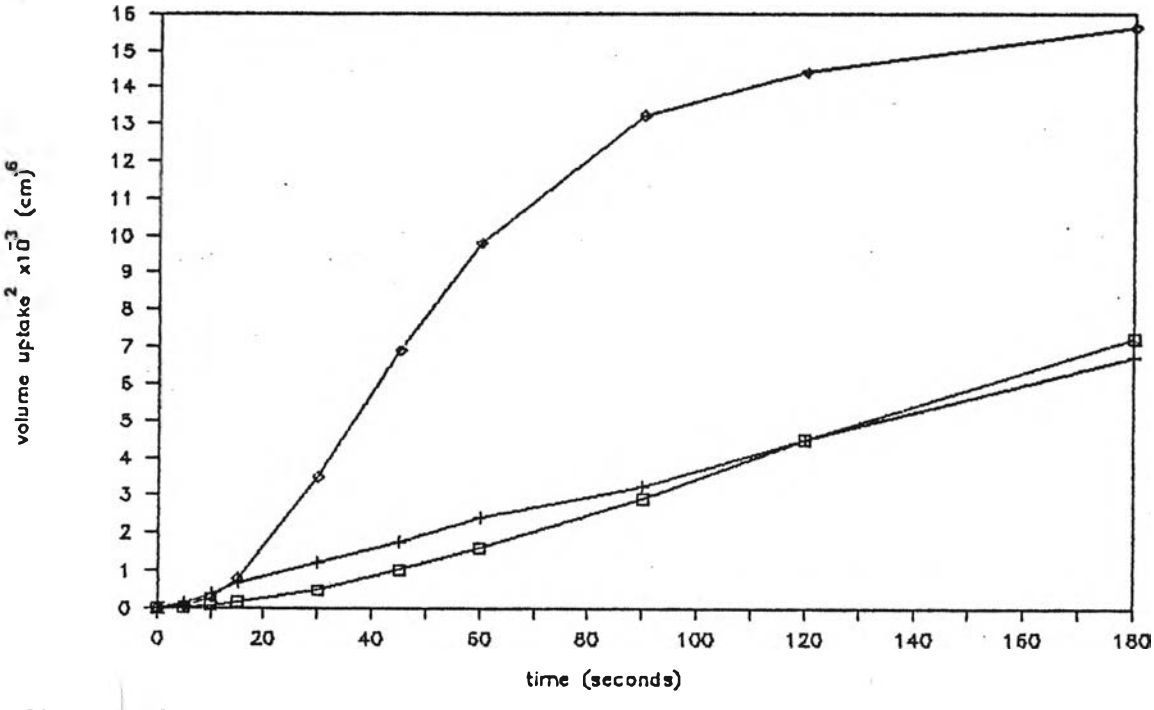


Figure 75 Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing Ac-di-Sol at 5% concentration as a function of time. □ 500 kg, + 1000 kg, ◊ 1500 kg.

Figures 76-77. At 0.5 and 1% concentration of corn starch, water penetration was not found at all conditions studied. At 2% level of corn starch, water penetration rate of tablets compressed at 500 kg was higher than those compressed at 1,000 and 1,500 kg. However, at 5% level, those which compressed at 1,000 kg show higher rate than at 500 kg. As the concentration of corn starch increased from 2 to 5%, the rate of water uptake also increased whereas lag time showed tendency to decrease.

4.2 Water soluble diluent

The results of water penetration for α-lactose monohydrate and corn starch tablets directly compressed at the three compressional forces are shown in Figures 78-81. At the concentration of corn starch < 2%, water uptake decreased on increasing compressional force. The reduction in magnitude of different in rate and extent of water uptake at various compressional forces were found as concentration of corn starch approched 5% level. Surprisingly, at 5% level, the magnitude of water uptake at 1,500 kg compressional force appeared to be the highest. The lag time was also reduced as concentration of corn starch was added.

5. EXPLOTAB(R)

5.1 Water insoluble diluent

The results of water penetration into directly compressed dibasic calcium phosphate dihydrate tablet with Explotab(R) as disintegrant at three compressional forces are demonstrated in Figures 82-85. These figures indicated the inversely effect of compressional force with related to water penetration rate at 0.5 and 1% concentration of Explotab(R). But at higher concentration this effect become slightly. It was

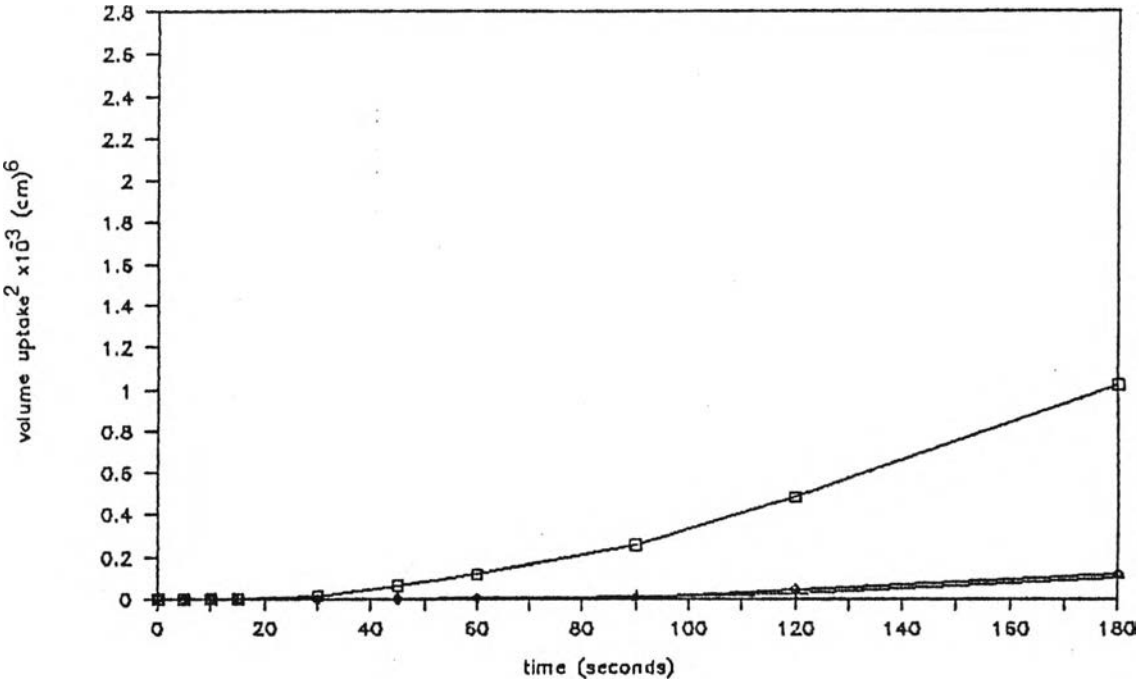


Figure 76 Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing corn starch at 2% concentration as a function of time. ▫ 500 kg, + 1000kg, ◊ 1500 kg.

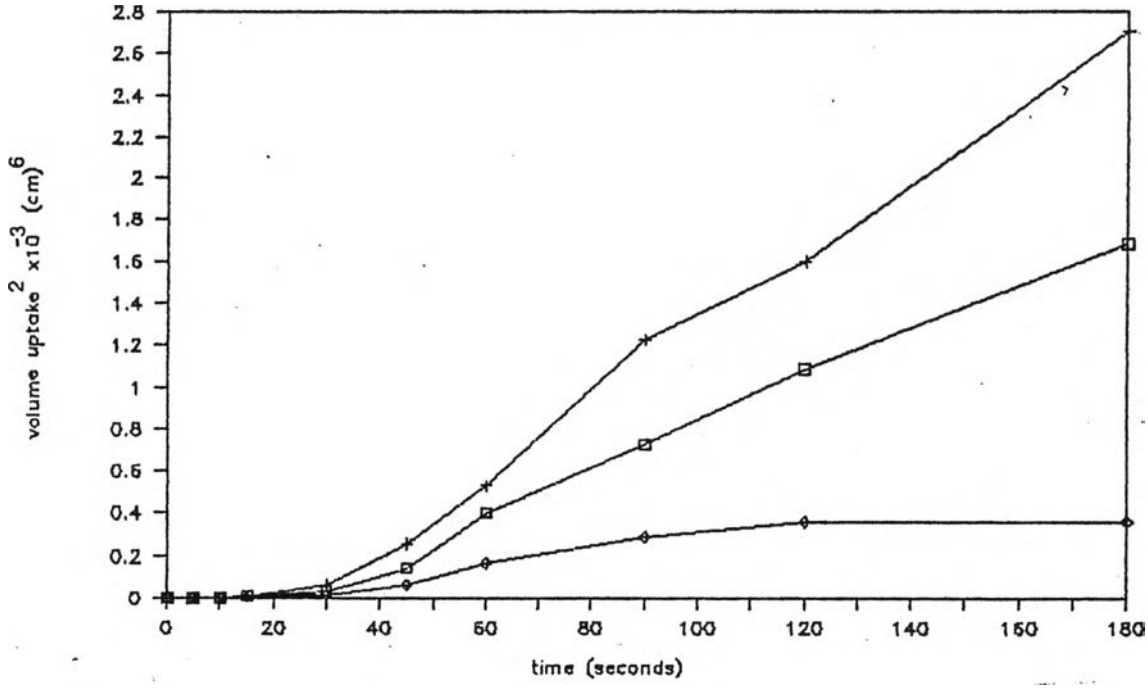


Figure 77 Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing corn starch at 5% concentration as a function of time. ▫ 500 kg, + 1000kg, ◊ 1500 kg.

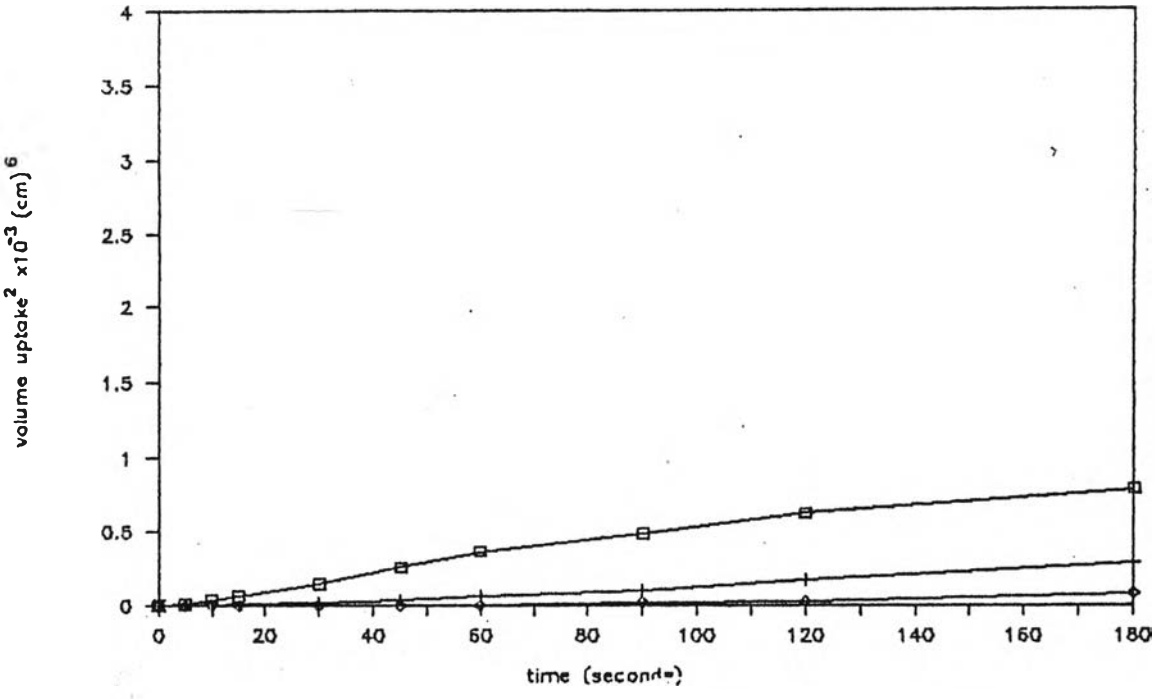


Figure 78 Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing corn starch at 0.5% concentration as a function of time.
□ 500 kg, + 1000 kg, ◊ 1500 kg.

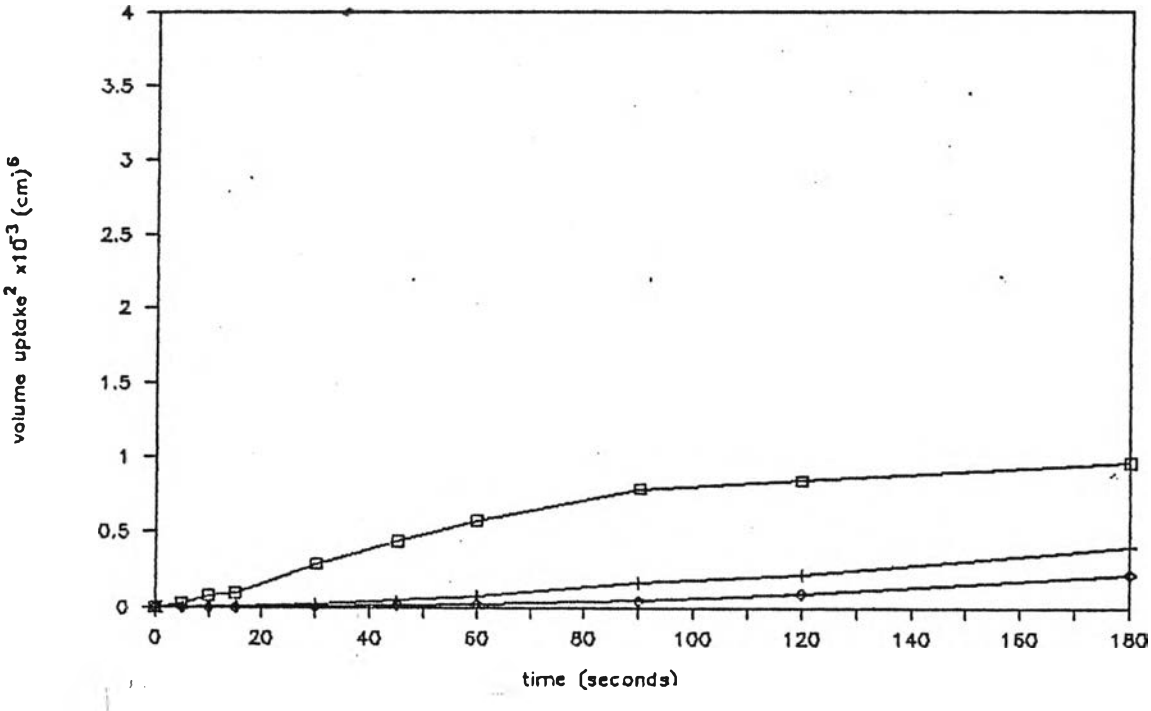


Figure 79 Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing corn starch at 1% concentration as a function of time.
□ 500 kg, + 1000 kg, ◊ 1500 kg.

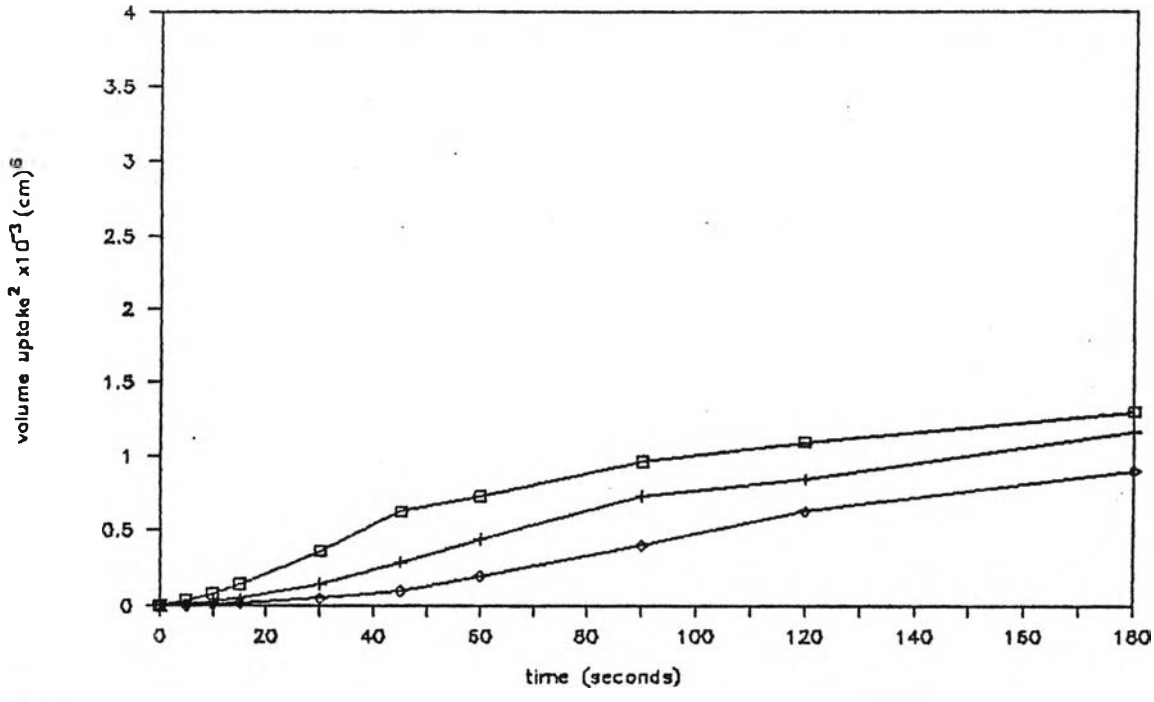


Figure 80 Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing corn starch at 2% concentration as a function of time.
□ 500 kg, + 1000 kg, ◇ 1500 kg.

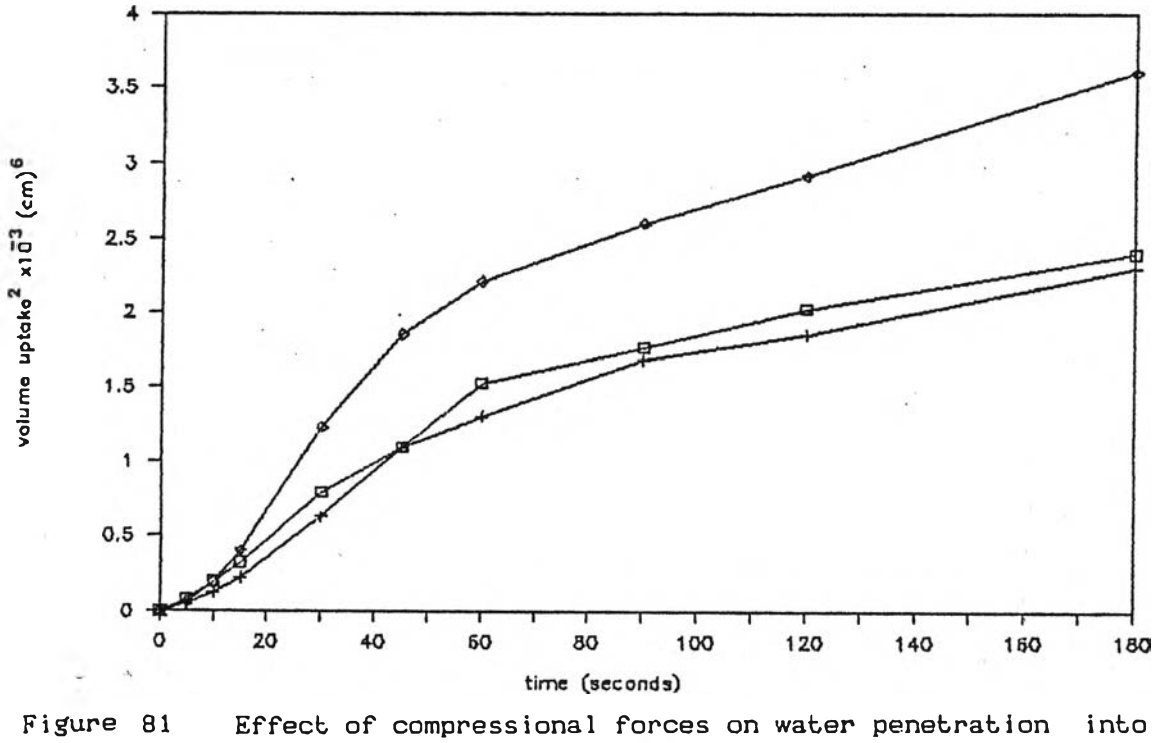


Figure 81 Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing corn starch at 5% concentration as a function of time.
□ 500 kg, + 1000 kg, ◇ 1500 kg.

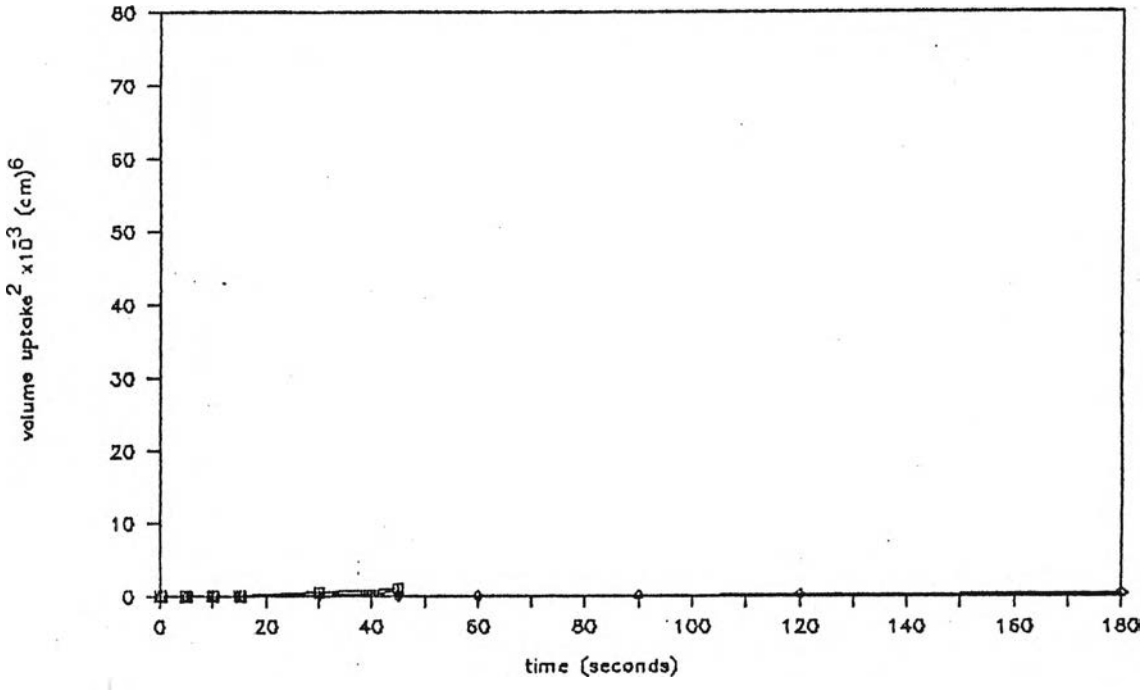


Figure 82 Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing Explotab at 0.5% concentration as a function of time. ▫ 500 kg, + 1000kg, ◇ 1500 kg.

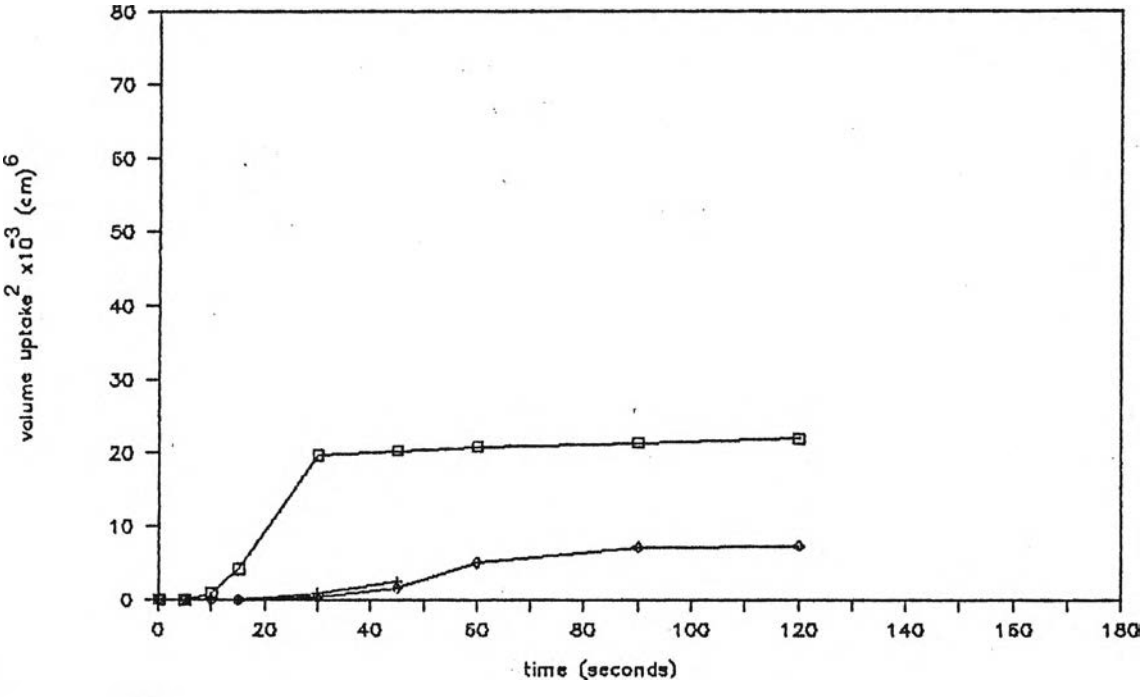


Figure 83 Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing Explotab at 1% concentration as a function of time. ▫ 500 kg, + 1000kg, ◇ 1500 kg.

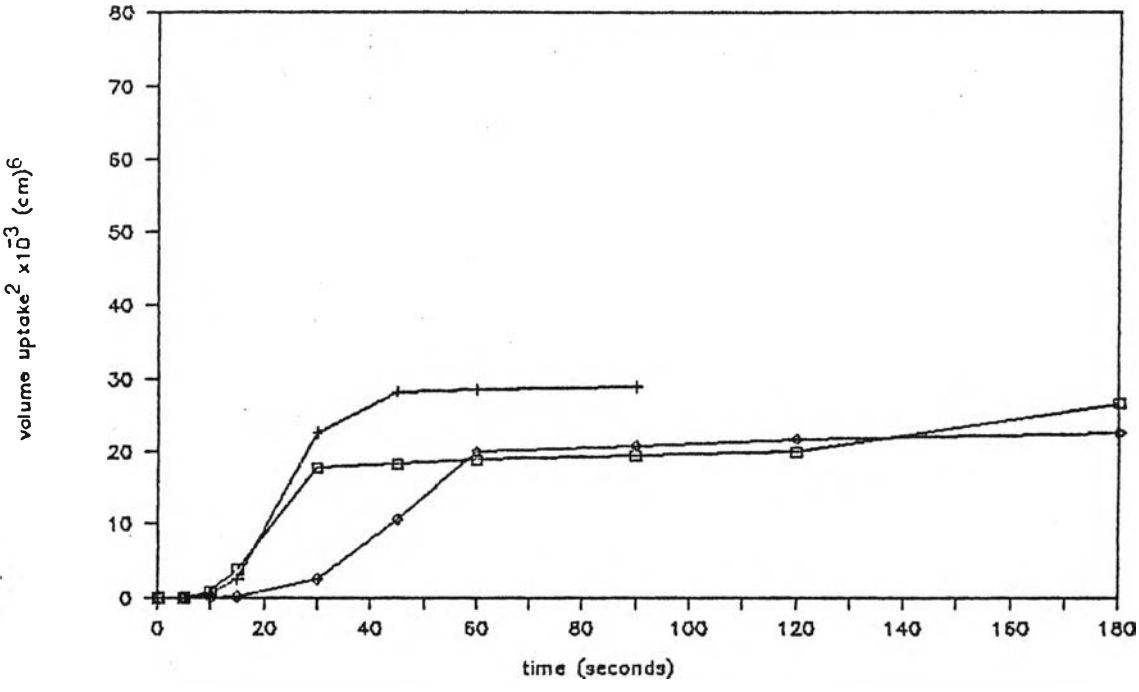


Figure 84 Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing Explotab at 2% concentration as a function of time. ▫ 500 kg, + 1000 kg, ◊ 1500 kg.

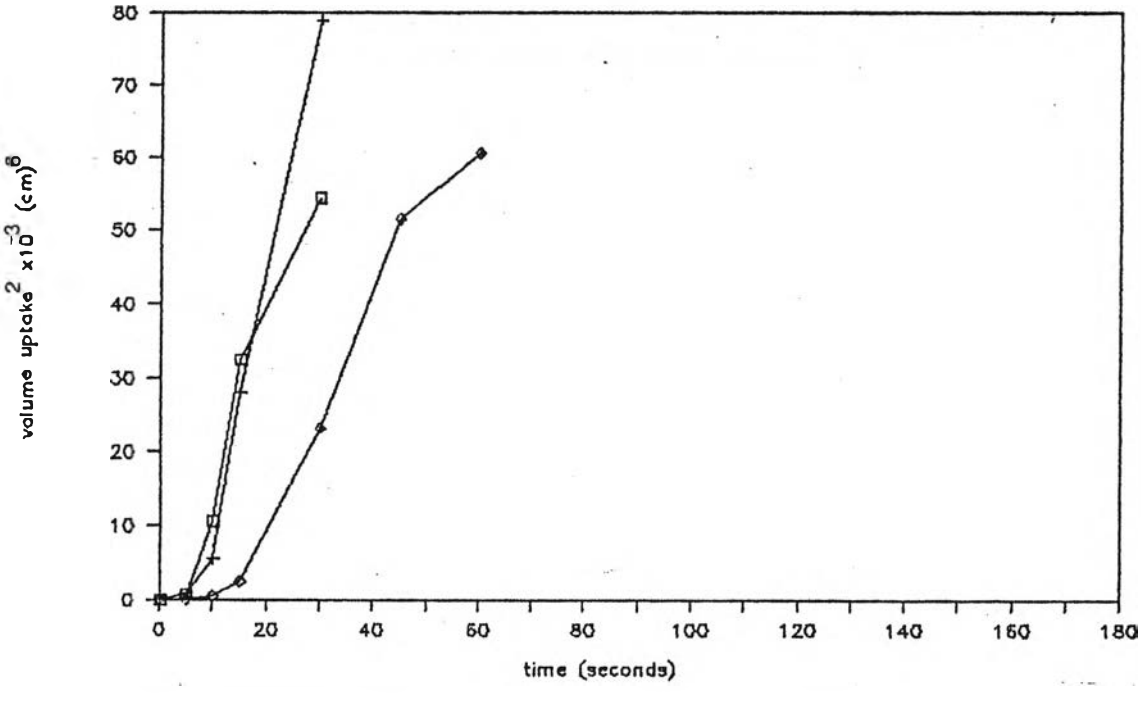


Figure 85 Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing Explotab at 5% concentration as a function of time. ▫ 500 kg, + 1000 kg, ◊ 1500 kg.

noticed that rate and extent of water uptake were strongly increased when increase the amount of Explotab(R).

5.2 Water soluble diluent

For α-lactose monohydrate and Explotab(R) system, the results are shown in Figures 86-89. At 0.5% level of Explotab(R), the rate of water uptake decrease as compressional force increased. On increasing amount of Explotab(R) in formulation, tablets which compressed at high compressional force tended to raise rapidly in rate and extent of water penetration, while those which compressed at 500 kg had tendency to decline. For example, the results of water penetration at 0.5% level were opposite from at 5% level. As the same as water insoluble system, water uptake increased on increasing concentration of Explotab(R).

6. KOLLIDON CL(R)

6.1 Water insoluble diluent

The influences of Kollidon CL(R) on the water penetration into dibasic calcium phosphate dihydrate tablets directly compressed at various compressional forces are shown in Figures 90-93. At 0.5% concentration the order of water penetrations as a function of compressional force are : 1000 - 500 > 1500 kg. However, at > 1% concentration the order become : 1000 > 1500 > 500 kg, respectively. It was obvious that at 5% Kollidon CL(R) the effect of compressional force on the rate of water penetration was minimized.

6.2 Water soluble diluent

In the case of α-lactose monohydrate containing Kollidon CL(R) directly compressed at three compressional forces, the water penetration curve are shown in

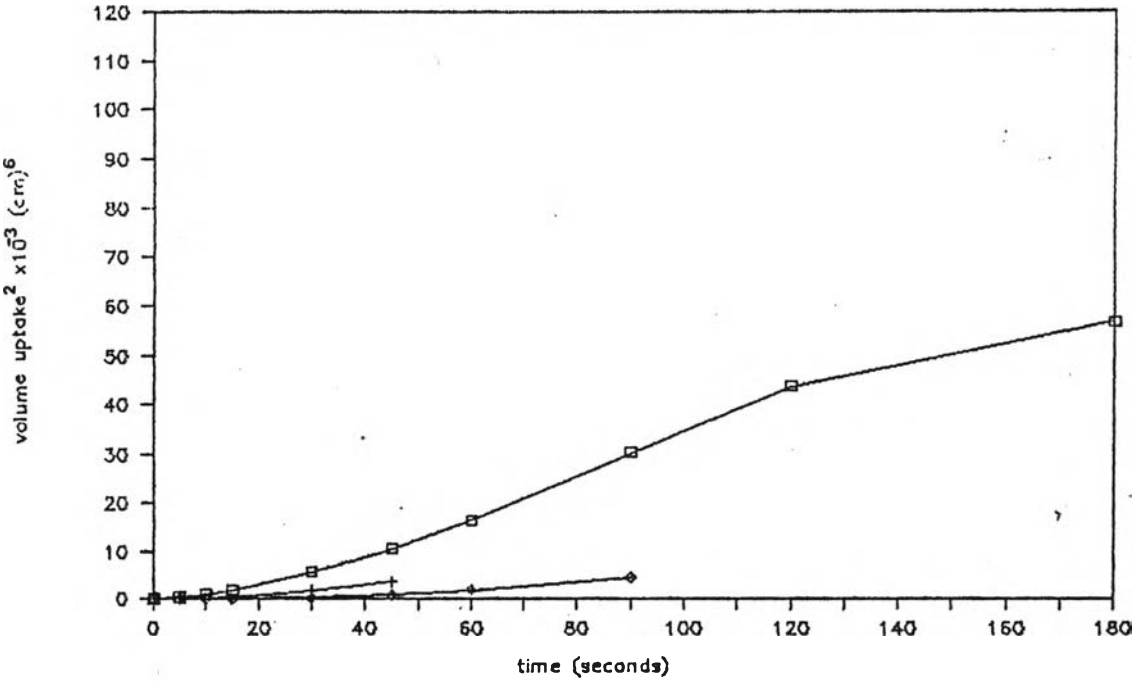


Figure 86. Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing Explotab at 0.5% concentration as a function of time. □ 500 kg, + 1000 kg, ◊ 1500 kg.

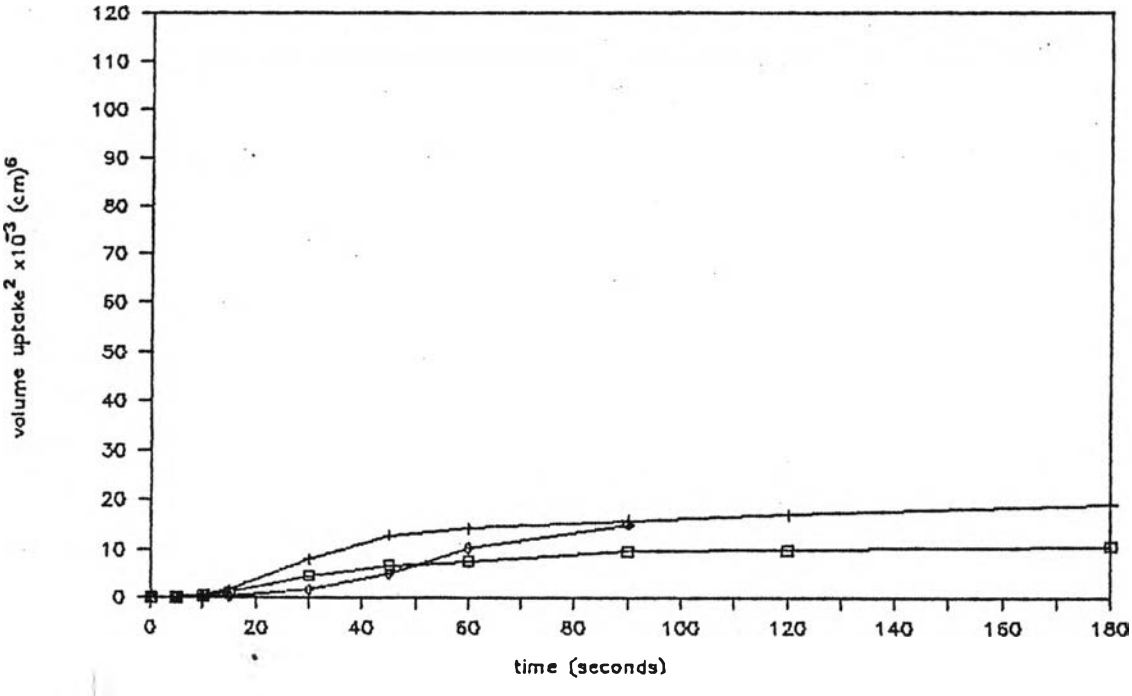


Figure 87. Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing Explotab at 1% concentration as a function of time □ 500 kg, + 1000 kg, ◊ 1500 kg.

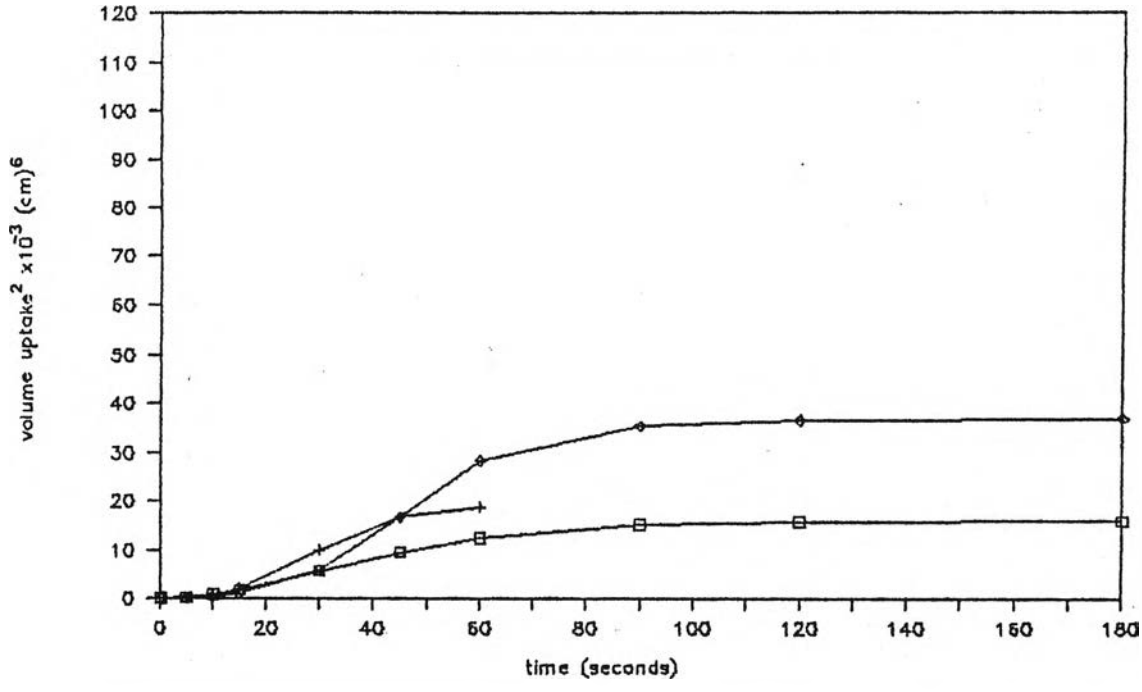


Figure 88. Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing Explotab at 2% concentration as a function of time. □ 500 kg, + 1000 kg, ◊ 1500 kg.

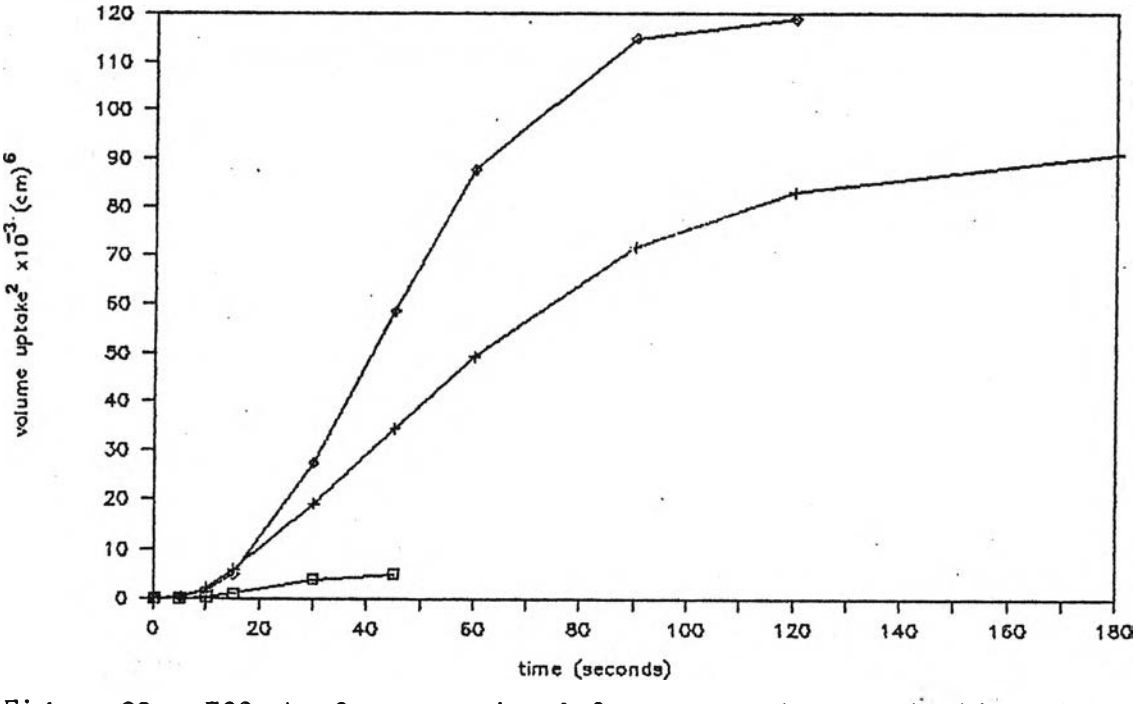


Figure 89. Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing Explotab at 5% concentration as a function of time. □ 500 kg, + 1000 kg, ◊ 1500 kg.

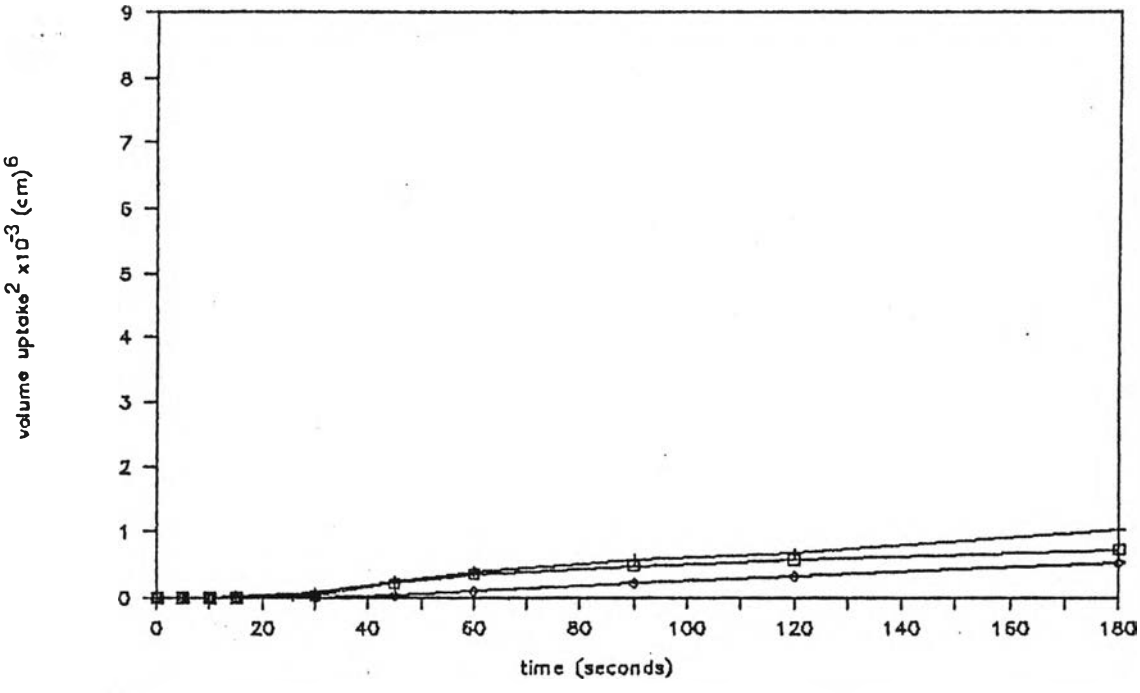


Figure 90. Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing Kollidon CL at 0.5% concentration as a function of time. ▫ 500 kg, + 1000 kg, ◇ 1500 kg.

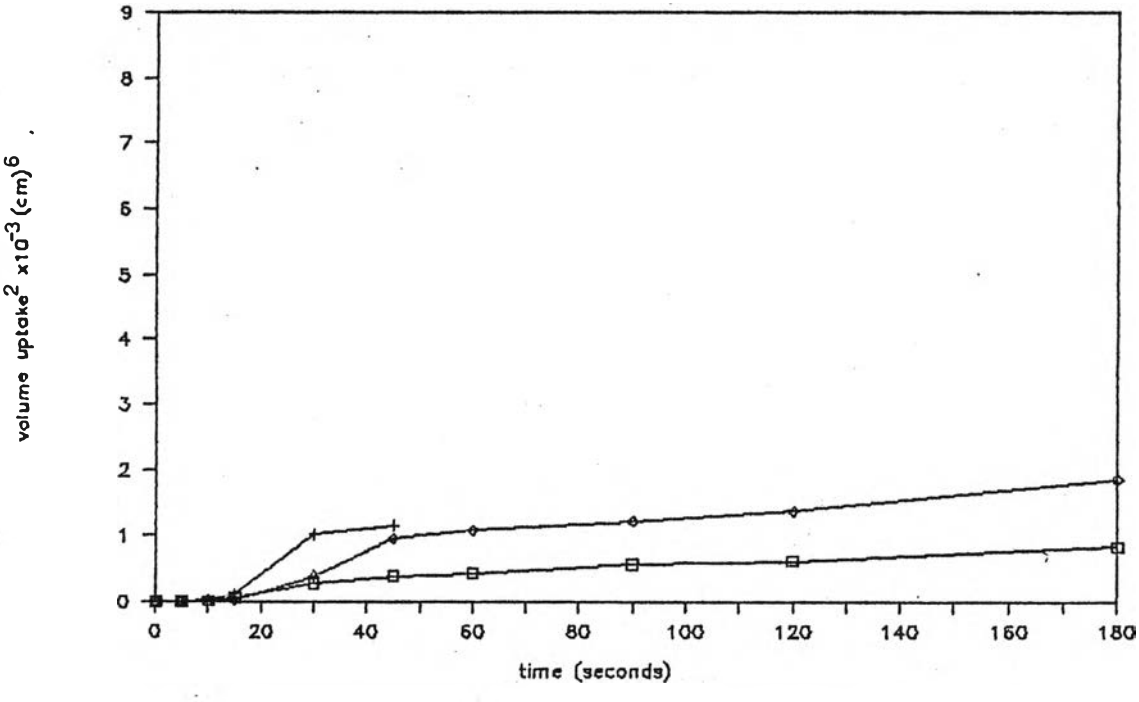


Figure 91. Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing Kollidon CL at 1% concentration as a function of time. ▫ 500 kg, + 1000 kg, ◇ 1500 kg.

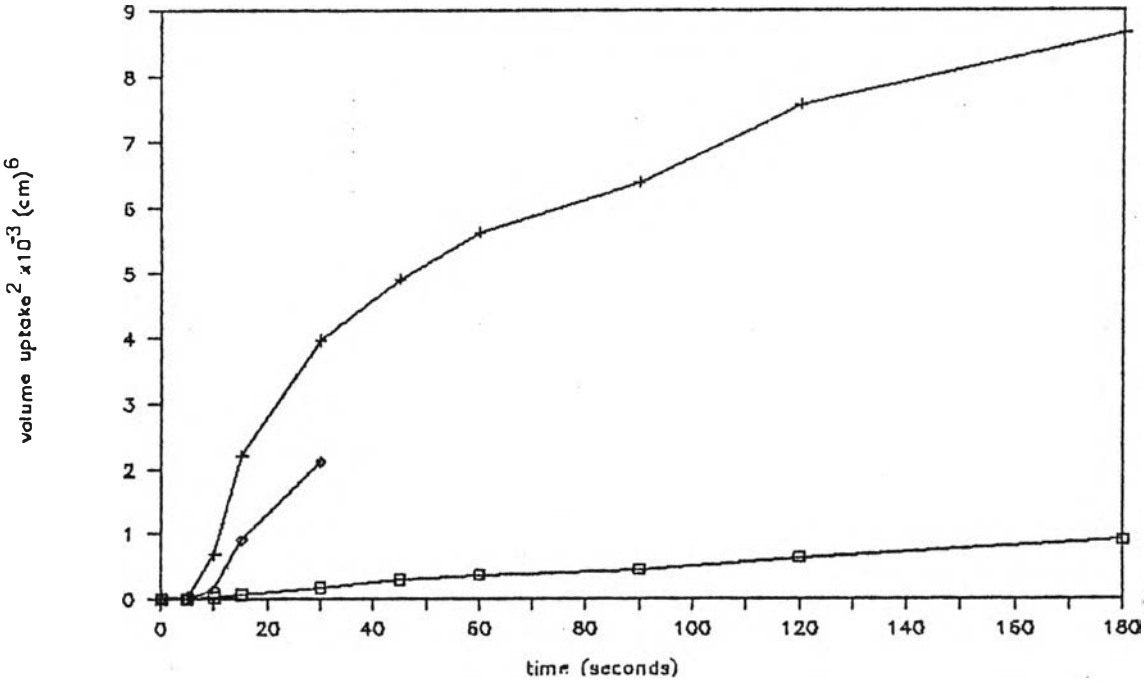


Figure 92. Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing Kollidon CL at 2% concentration as a function of time. ▫ 500 kg, + 1000 kg, ◊ 1500 kg.

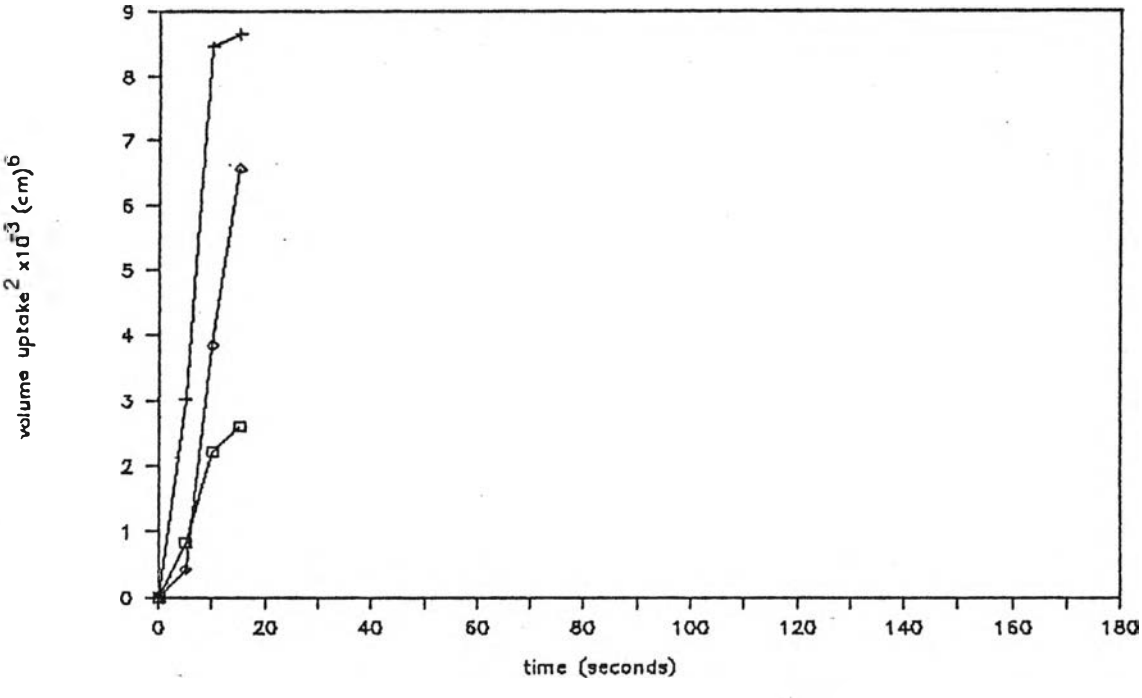


Figure 93. Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing Kollidon CL at 5% concentration as a function of time. ▫ 500 kg, + 1000 kg, ◊ 1500 kg.

Figures 94-97. In general, it seemed that water uptake was directly related to compressional force except at 0.5% level. This effect was more pronounced at higher concentration of Kollidon CL(R) and the higher compressional force showed higher rate of water uptake. As concentration of Kollidon CL(R) increased, water uptake at all compressional forces was gradually increased.

7. NYMCEL(R)

7.1 Water insoluble diluent

The results of water penetration for dibasic calcium phosphate dihydrate tablets containing Nymcel(R) when directly compressed at three compressional forces are demonstrated in Figures 98-101 . The water penetration rate decreased with increasing compressional force, especially at compressional force of 1,500 kg the rate of water uptake was slowed and had long lag time. However, at higher amount of Nymcel(R), the influence of compressional force on lag time was hindered by the strongly increase in water uptake rate.

7.2 Water soluble diluent

In the case of α-lactose monohydrate system, compressional force exerted influence on water penetration rate in the similar fashion to Kollidon CL(R) as seen in Figures 102-105. The higher the concentration of Nymcel(R) adding, the better the rate and extent of water uptake (except at 5% level). It was obvious that higher compressional force resulted in higher rate of water uptake. At 5% concentration, however, the rate of water uptake became smaller as compared with other concentrations.

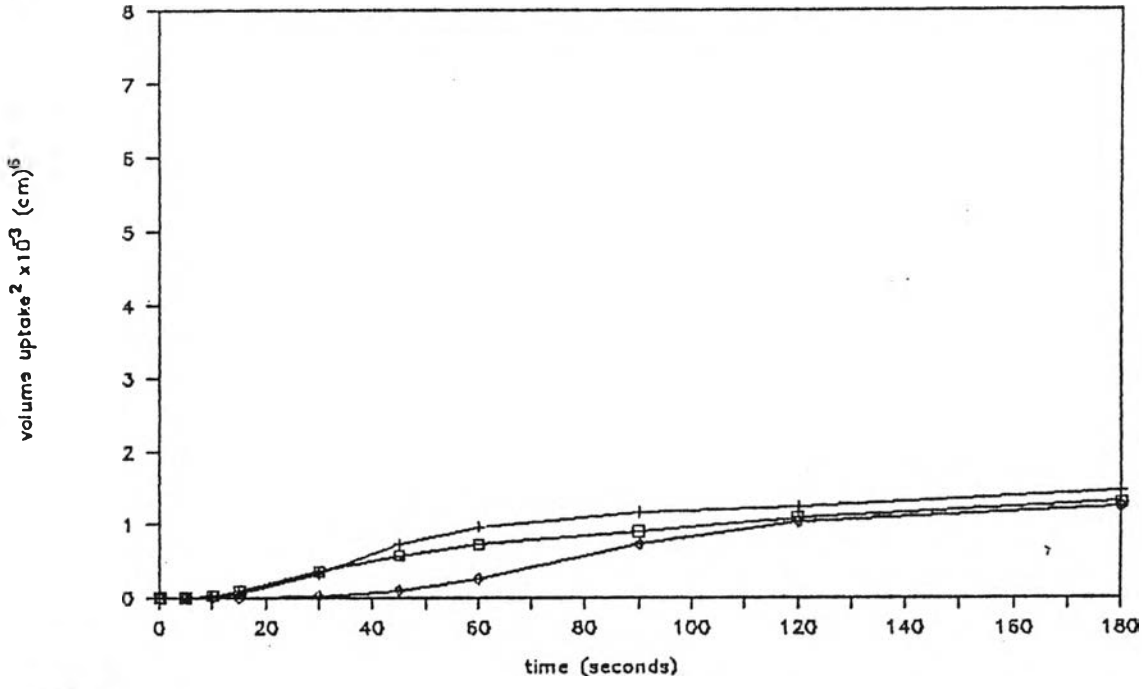


Figure 94. Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing Kollidon CL at 0.5% concentration as a function of time.
▫ 500 kg, + 1000 kg, ◇ 1500 kg.

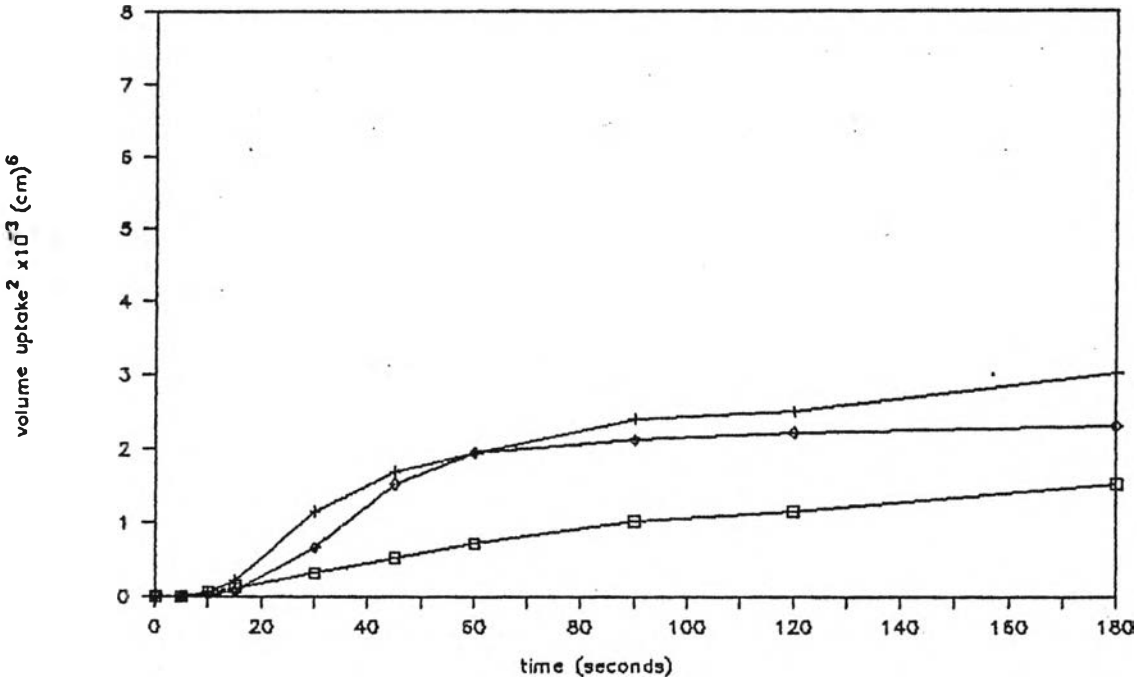


Figure 95. Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing Kollidon CL at 1% concentration as a function of time.
▫ 500 kg, + 1000 kg, ◇ 1500 kg.

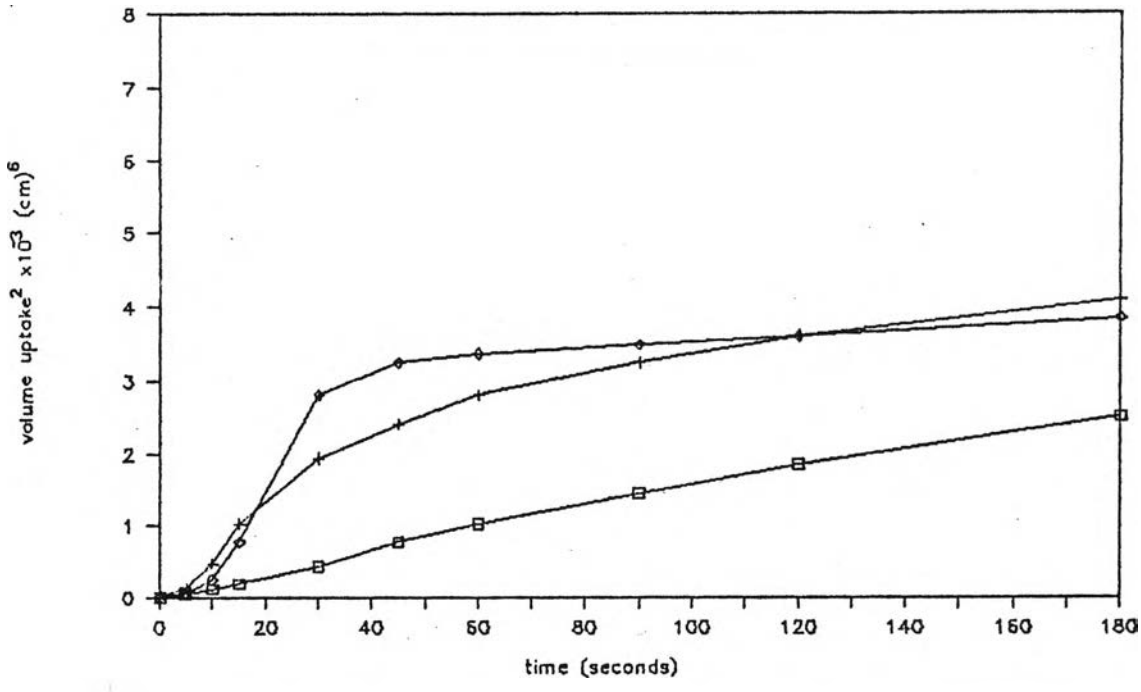


Figure 96. Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing Kollidon CL at 2% concentration as a function of time.
□ 500 kg, + 1000 kg, ◇ 1500 kg.

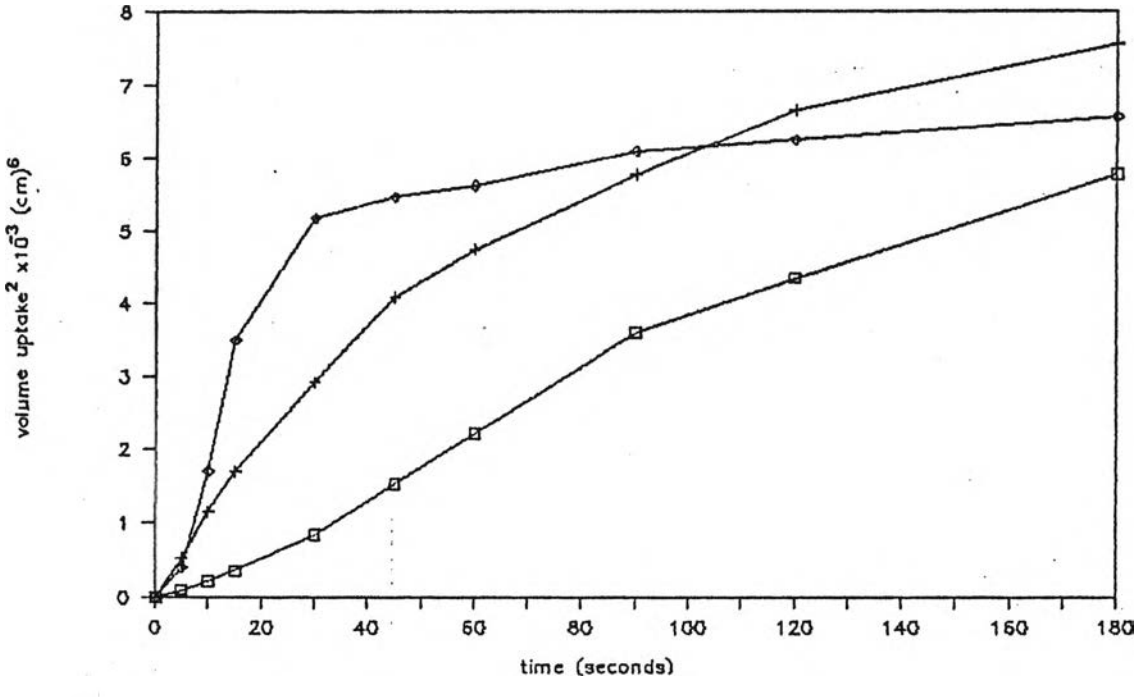


Figure 97. Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing Kollidon CL at 5% concentration as a function of time.
□ 500 kg, + 1000 kg, ◇ 1500 kg.

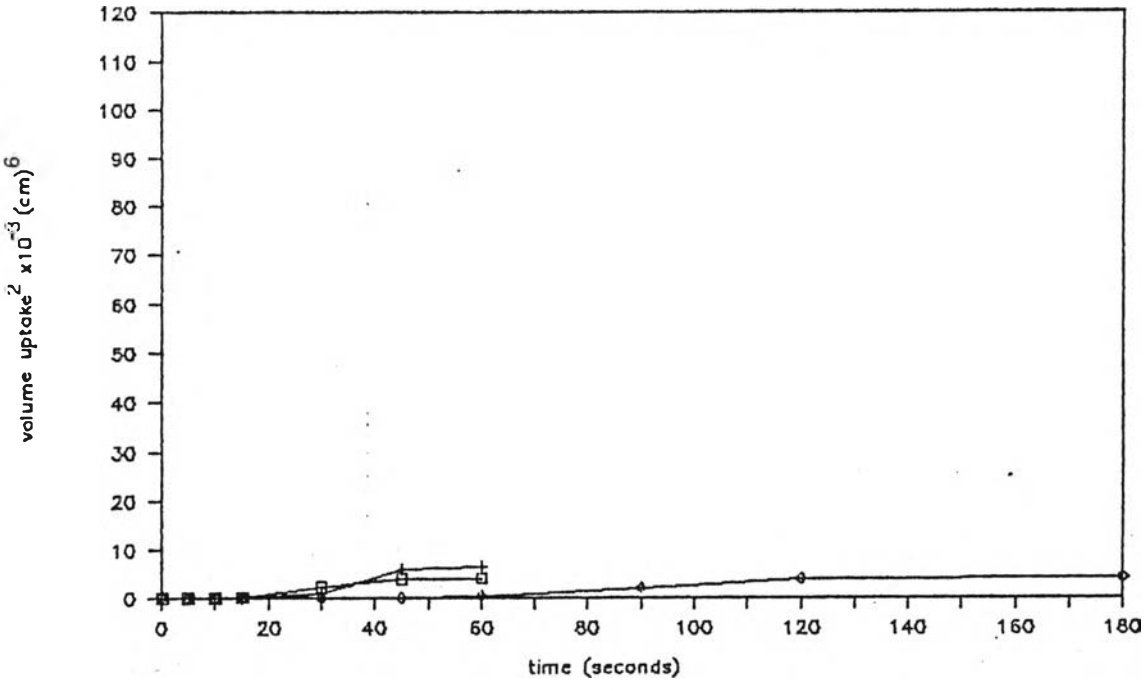


Figure 98. Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing Nymcel at 0.5% concentration as a function of time. ▫ 500 kg, + 1000 kg, ◊ 1500 kg.

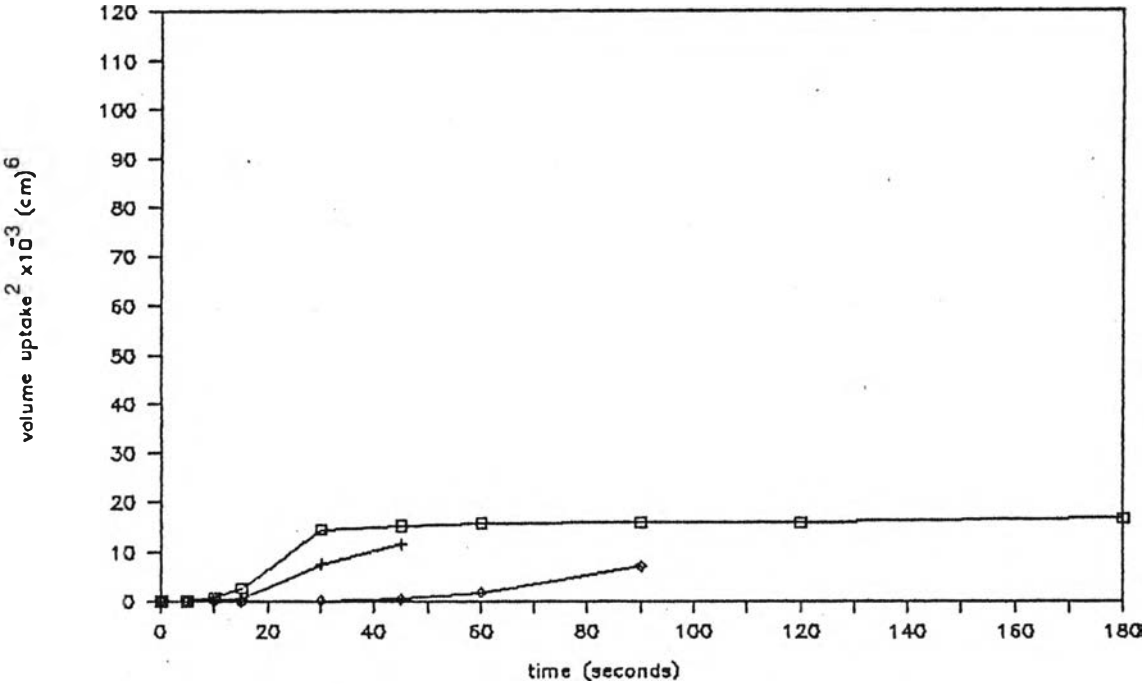


Figure 99. Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing Nymcel at 1% concentration as a function of time. ▫ 500 kg, + 1000 kg, ◊ 1500 kg.

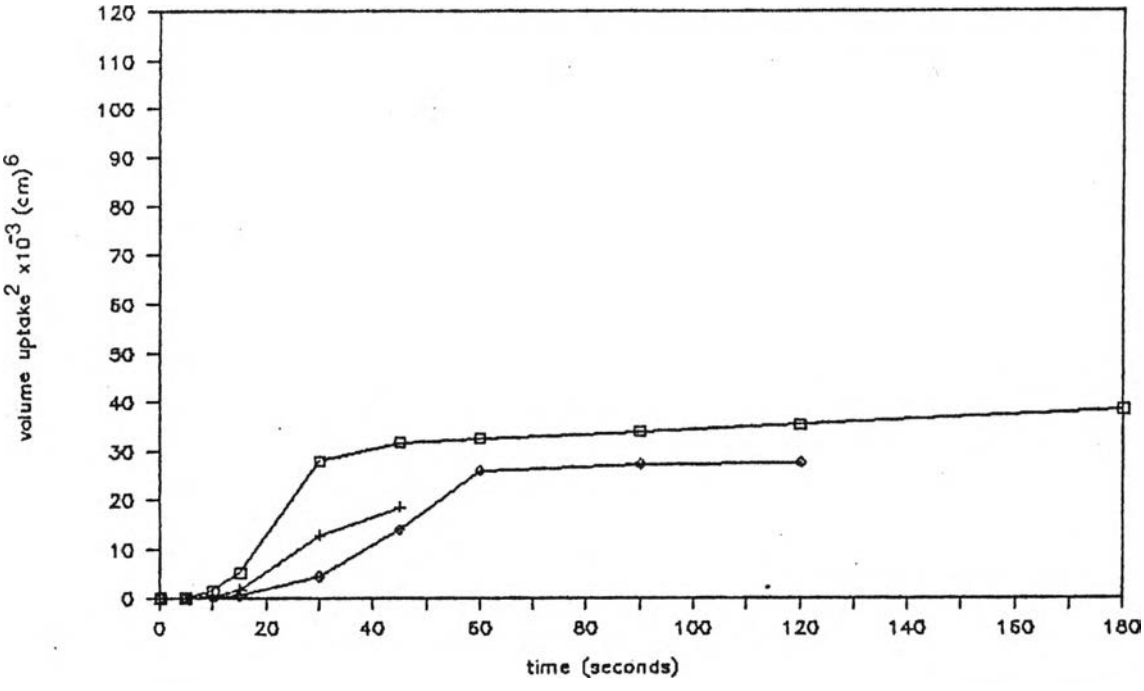


Figure 100 Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing Nymcel at 2% concentration as a function of time. □ 500 kg, + 1000 kg, ◊ 1500 kg.

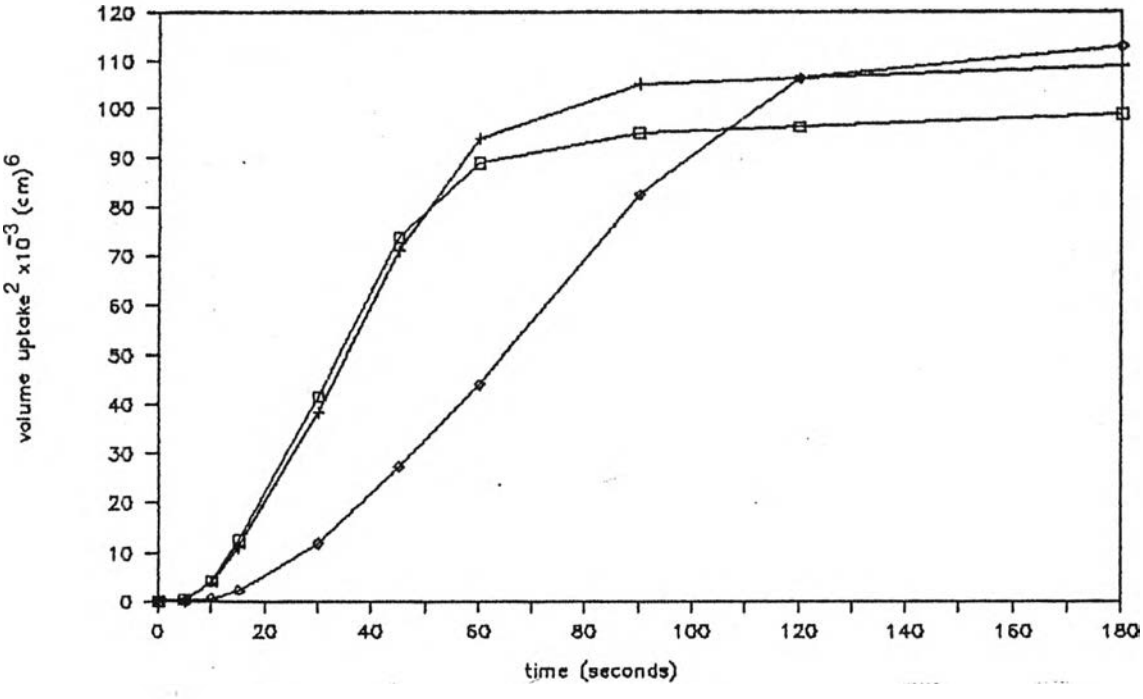


Figure 101. Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing Nymcel at 5% concentration as a function of time. □ 500 kg, + 1000 kg, ◊ 1500 kg.

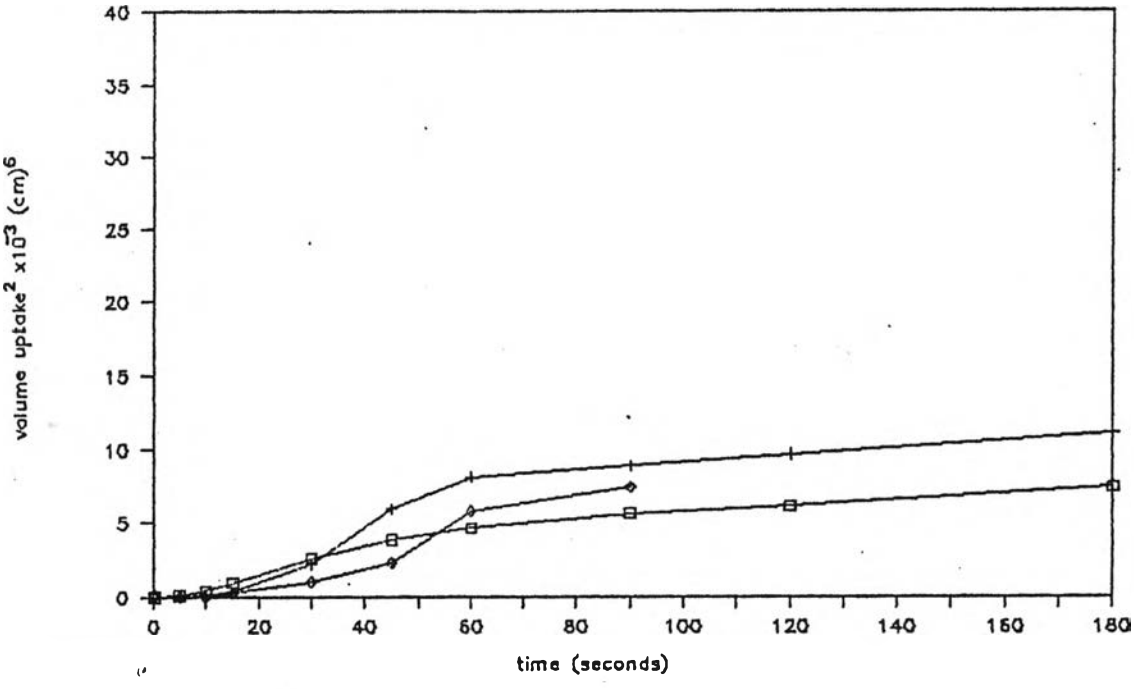


Figure 102. Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing Nymcel at 0.5% concentration as a function of time. □ 500 kg, + 1000 kg, ◊ 1500 kg.

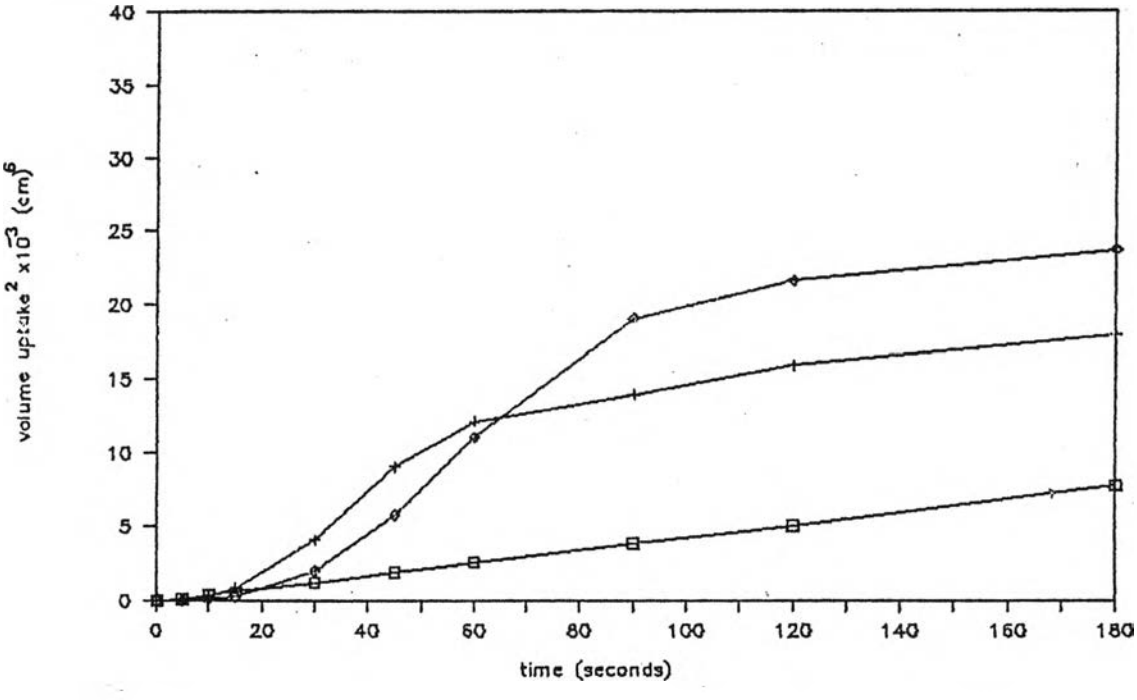


Figure 103 Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing Nymcel at 1% concentration as a function of time. □ 500 kg, + 1000 kg, ◊ 1500 kg.

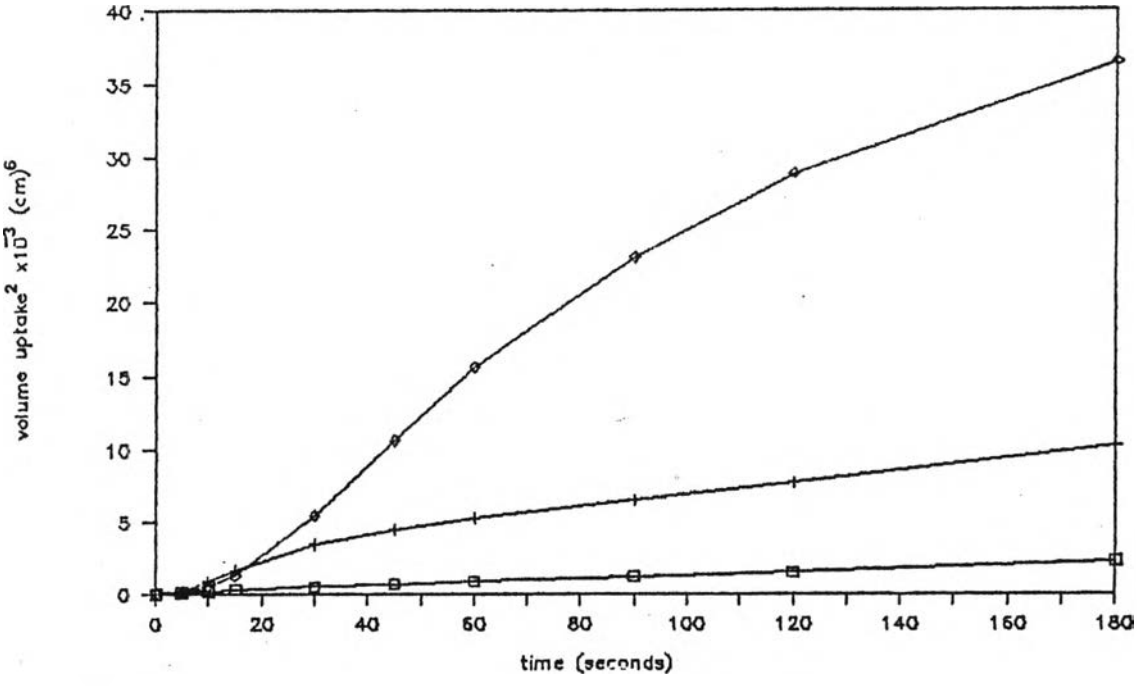


Figure 104. Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing Nymcel at 2% concentration as a function of time. □ 500 kg, + 1000 kg, ◇ 1500 kg.

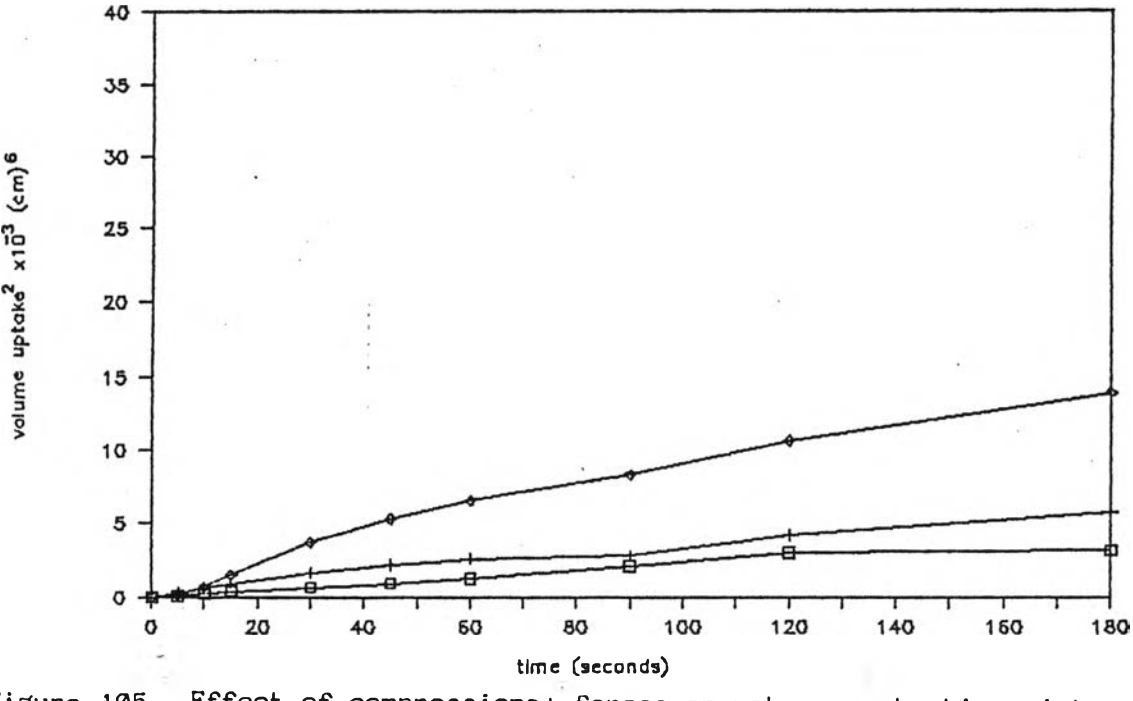


Figure 105. Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing Nymcel at 5% concentration as a function of time. □ 500 kg, + 1000 kg, ◇ 1500 kg.

8. STARCH 1500®

8.1 Water insoluble diluent

The effect of Starch 1500® upon water penetration of directly compressed dibasic calcium phosphate dihydrate system at three compressional forces are shown in Figures 106-109. At 0.5% concentration of Starch 1500®, the occurence of water penetration was not found. As well as other disintegrants mentioned before, the rate of water uptake was influenced by compressional force, especially at 1500 kg the water uptake didn't occur until at higher concentration of 5% level. Incorporation of more concentration of Starch 1500® into dibasic calcium phosphate dihydrate tablets had slight effect on water penetration rate.

8.2 Water soluble diluent

For α-lactose monohydrate system, Starch 1500® behaved in the similar way to water insoluble diluent as shown in Figures 110-113 At 0.5% concentration of Starch 1500®, water penetration was not observed at compressional forces of 1,000 and 1,500 kg. Water uptake still depend inversely on compressional forces.However, at high concentration the magnitude of difference of water uptake among various compressional forces was slightly.In addition,effect of concentration of Starch 1500® on water penetration rate in α-lactose monohydrate system was more pronounced than in water insoluble system.

The Evaluation of Hydrochlorothiazide Tablets

Hydrochlorothiazide tablets, prepared by direct compression using dibasic calcium phosphate dihydrate as diluent and D_1, D_2, Explotab® and corn starch as disintegrant, were observed for their physical properties as follows : (a) weight variation (b) thickness (c) hardness (d) friability (e)

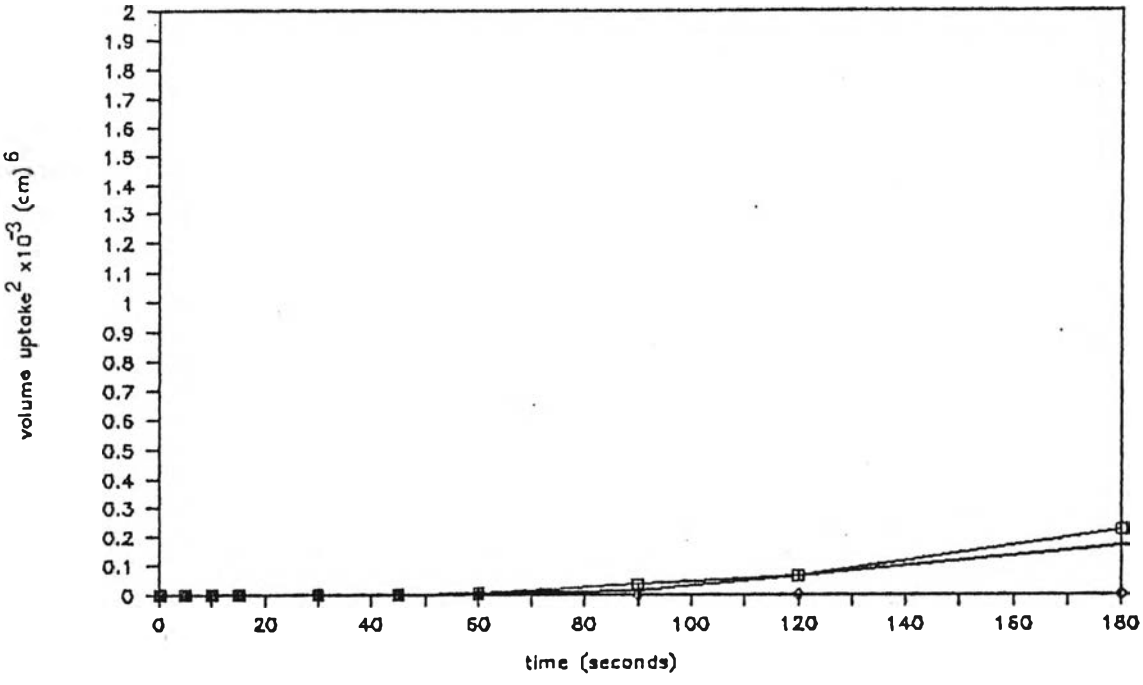


Figure 106. Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing Starch 1500 at 0.5% concentration as a function of time. ▫ 500 kg, + 1000 kg, ◊ 1500 kg.

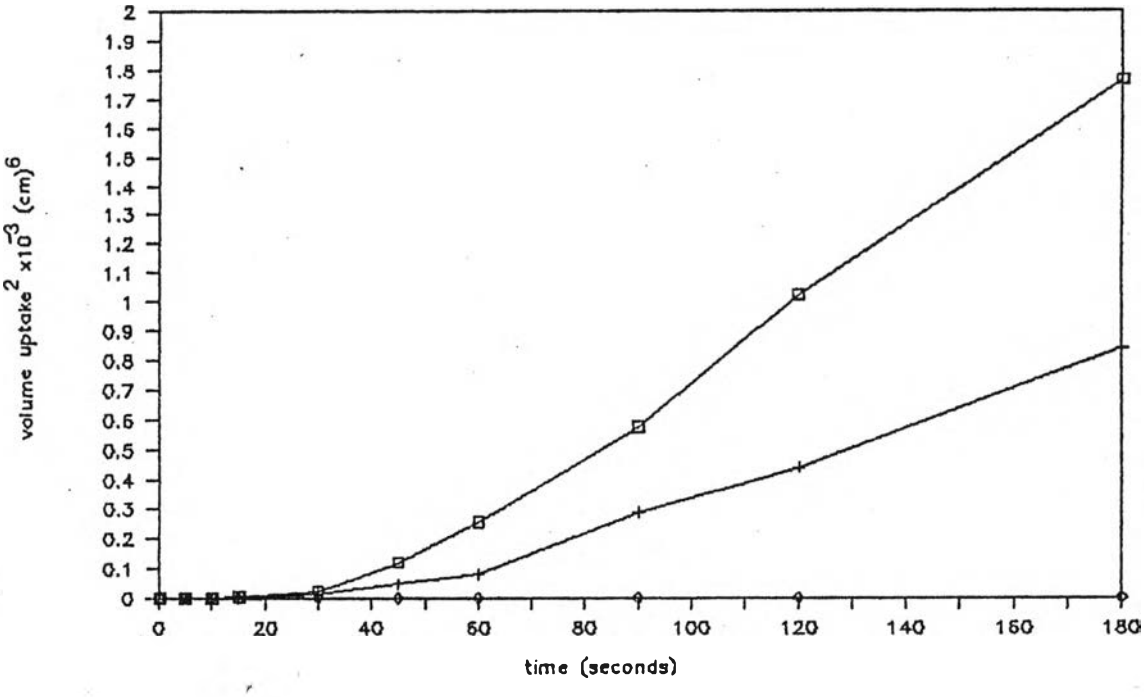


Figure 107. Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing Starch 1500 at 1% concentration as a function of time. ▫ 500 kg, + 1000 kg, ◊ 1500 kg.

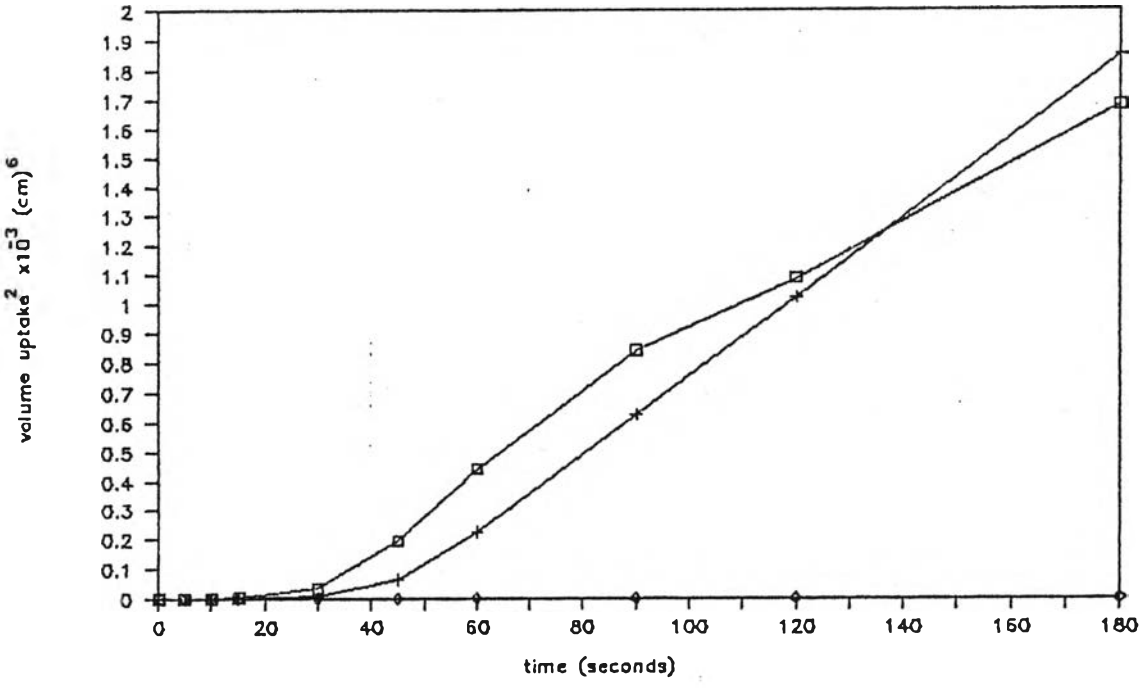


Figure 108. Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing Starch 1500 at 2% concentration as a function of time. □ 500 kg, + 1000 kg, ◊ 1500 kg.

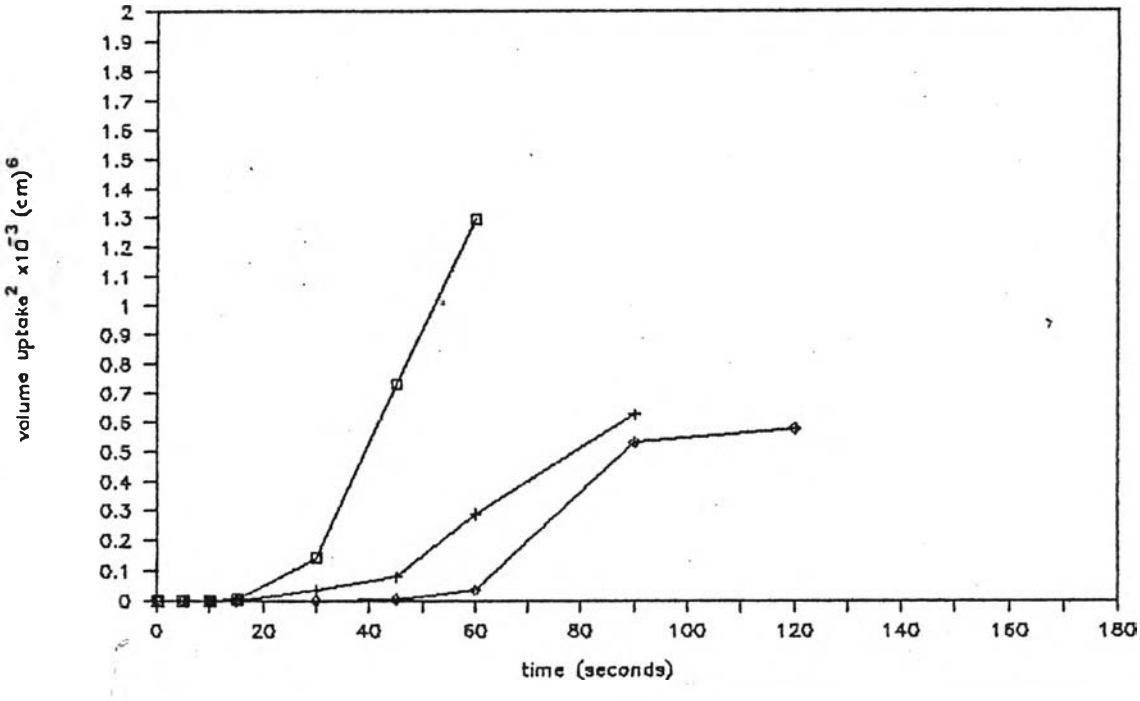


Figure 109. Effect of compressional forces on water penetration into dibasic calcium phosphate dihydrate tablets containing Starch 1500 at 5% concentration as a function of time. □ 500 kg, + 1000 kg, ◊ 1500 kg.

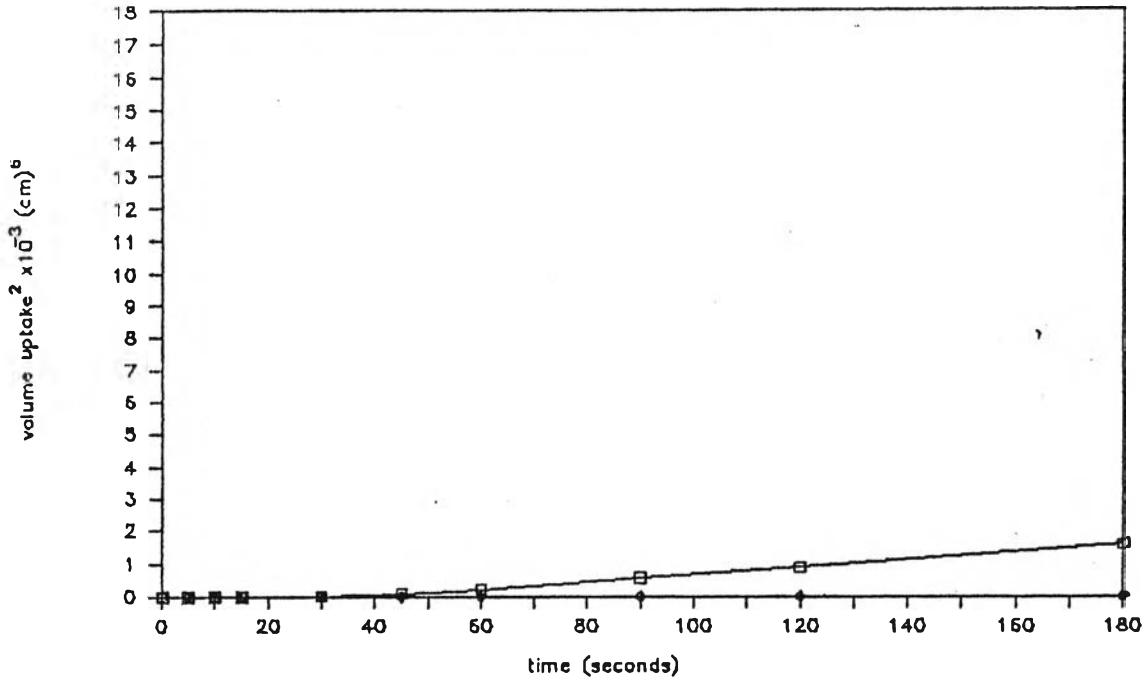


Figure 110 Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing Starch 1500 at 0.5% concentration as a function of time.
□ 500 kg, + 1000 kg, ◊ 1500 kg.

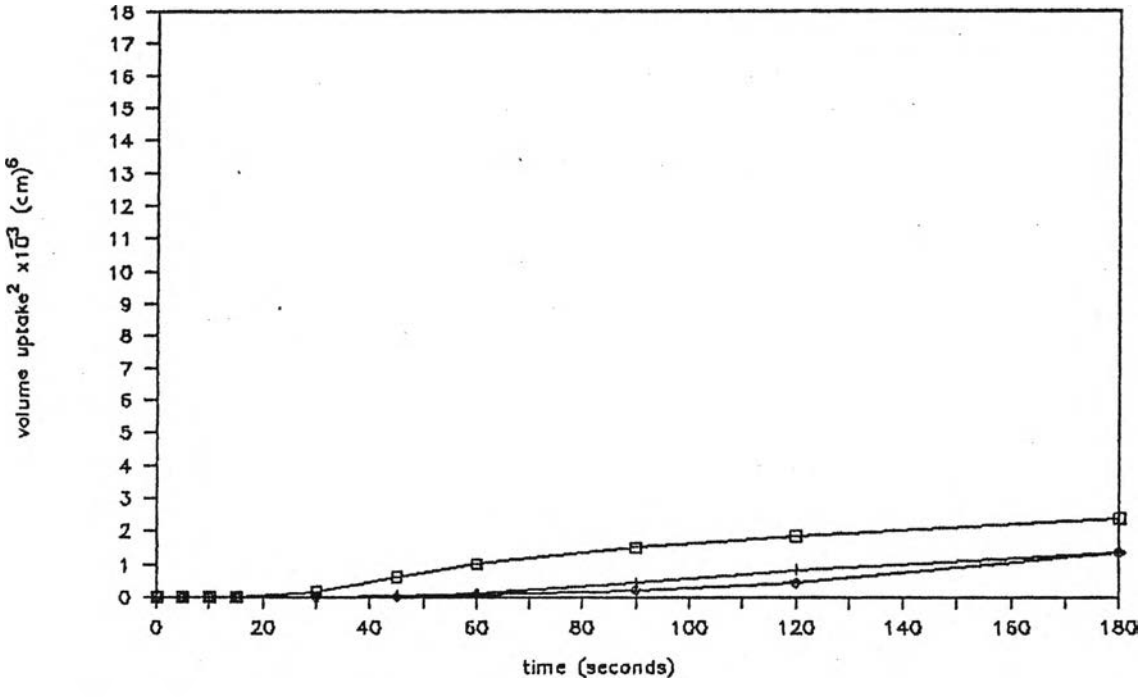


Figure 111. Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing Starch 1500 at 1% concentration as a function of time.
□ 500 kg, + 1000 kg, ◊ 1500 kg.

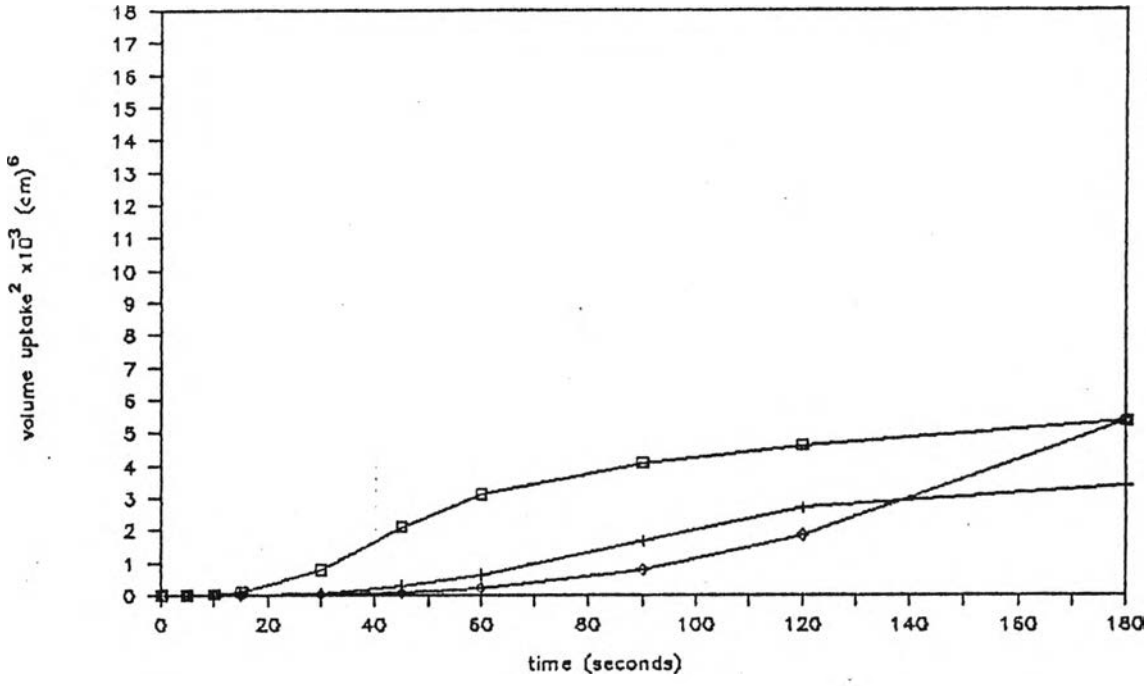


Figure 112. Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing Starch 1500 at 2% concentration as a function of time.
▫ 500 kg, + 1000 kg, ◇ 1500 kg.

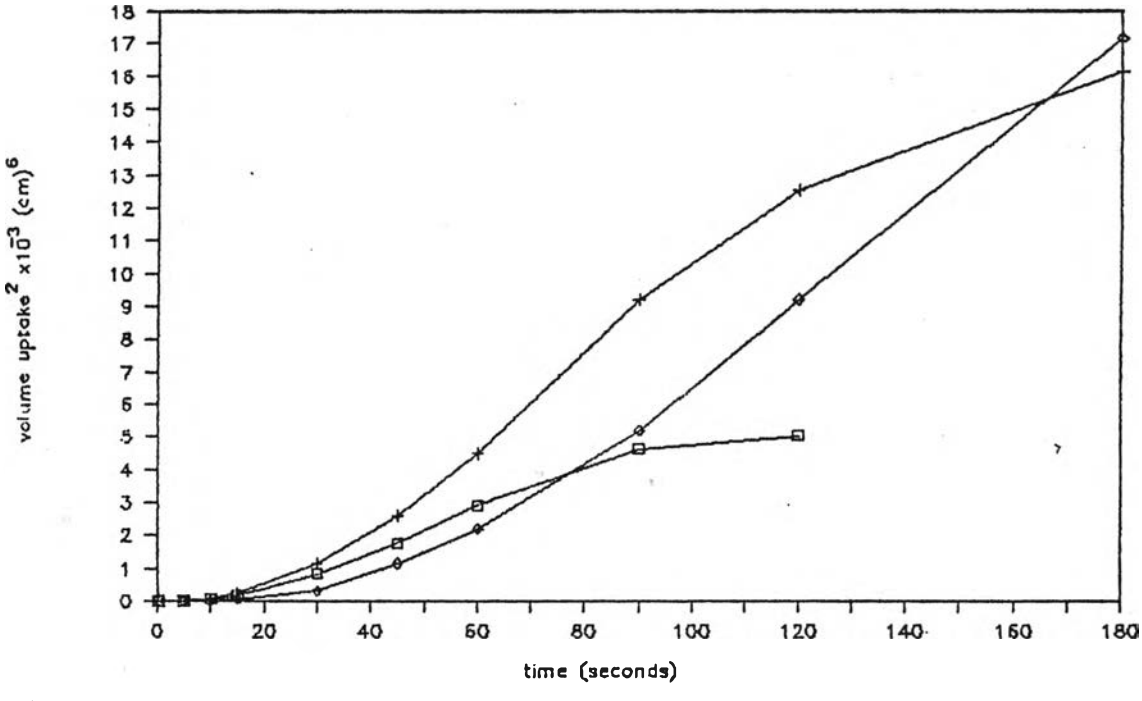


Figure 113. Effect of compressional forces on water penetration into α-lactose monohydrate tablets containing Starch 1500 at 5% concentration as a function of time.
▫ 500 kg, + 1000 kg, ◇ 1500 kg.

content uniformity (f) disintegration time and (g) dissolution of tablets. Data from these measurements are shown in Tables 28-29 and Figures 114-115.

(a-d) Weight variation, Thickness, Hardness and Friability.

The average value and standard deviation of weight, thickness and hardness for hydrochlorothiazide tablets are shown in Table 28. In all cases, weight variation of tablets were well within the limit of USP standard. For thickness, the significant difference was not found among formulations. The hardness of tablets were found to be in the range of 7 ± 1 kg. The friability of tablets were within acceptable Limitted (< 1%).

(e) Content Uniformity of Tablets

The results of average content, standard deviation and percent labelled amount of hydrochlorothiazide tablets containing different disintegrants are shown in Table 29. In all cases, content uniformity of tablets were well within the limit of USP standard.

(f) Disintegration time of Tablets

The disintegration time of hydrochlorothiazide tablets are shown in Table 28. For all formulations, disintegration time were reduced significantly from the control and from the formulations containing starch which showed no disintegration after 30 minutes. Increasing concentration of D_1 and D_2 from 1 to 2% obviously reduced disintegration time whereas no significant difference was found for Explotab(R) formulations. At both 1 and 2% concentration, the disintegration time of D_2 was slightly shorter than D_1.

Table 28

Physical Properties of Hydrochlorothiazide in Dibasic Calcium Phosphate Dihydrate Tablets Containing D_1, D_2, Corn Starch and Explotab(R) at 1 and 2% as Disintegrants.

Disintegrant	-	D_1		D_2		Corn starch		Explotab(R)	
%	-	1	2	1	2	1	2	1	2
weight (mg.) (± S.D.)	356.1 (0.011)	350.8 (0.006)	351.8 (0.008)	352.3 (0.034)	352.4 (0.018)	351.6 (0.012)	354.4 (0.076)	354.5 (0.006)	354.9 (0.005)
thickness(mm.) (± S.D.)	3.226 (0.011)	3.157 (0.006)	3.216 (0.008)	3.215 (0.034)	3.250 (0.018)	3.213 (0.012)	3.189 (0.076)	3.200 (0.006)	3.210 (0.005)
hardness(kg.) (± S.D.)	6.73 (0.36)	7.58 (0.50)	6.42 (0.52)	7.28 (0.34)	6.21 (0.46)	6.86 (0.46)	6.64 (0.65)	7.69 (0.23)	7.03 (0.86)
% friability	0.38	0.31	0.29	0.31	0.34	0.37	0.20	0.34	0.35
disintegration time (sec)	>30min	778.33	123.83	611.67	102.5	>30min	>30min	45.5	45.8
(range)	(ALL)	(605-1,080)	(90-143)	(410-1,050)	(87-108)	(ALL)	(ALL)	(37-55)	(35-60)

Table29

Content Uniformity and Percent Labelled Amount of Hydrochlorothiazide Tablets Containing D_1, D_2, Corn Starch and Explotab(R) at 1 and 2% as Disintegrants.

Disintegrant		content(mg.)* $\bar{X} \pm$ S.D.	% labelled amount * (range)
Blank		42.52±1.56	101.24 (97.55-105.88)
D_1	1%	42.23±1.49	100.55 (97.00-105.33)
	2%	42.24±0.75	100.57 (98.10-103.17)
D_2	1%	42.74±1.29	101.78 (97.55-105.14)
	2%	42.78±0.82	101.88 (93.90-105.33)
Corn Starch	1%	41.79±1.36	99.50 (94.45-103.88)
	2%	42.07±1.17	100.17 (98.45-104.43)
Explotab(R)	1%	42.50±1.19	101.19 (98.45-104.98)
	2%	42.17±1.34	100.40 (98.64-104.43)

* average from 10 tablets

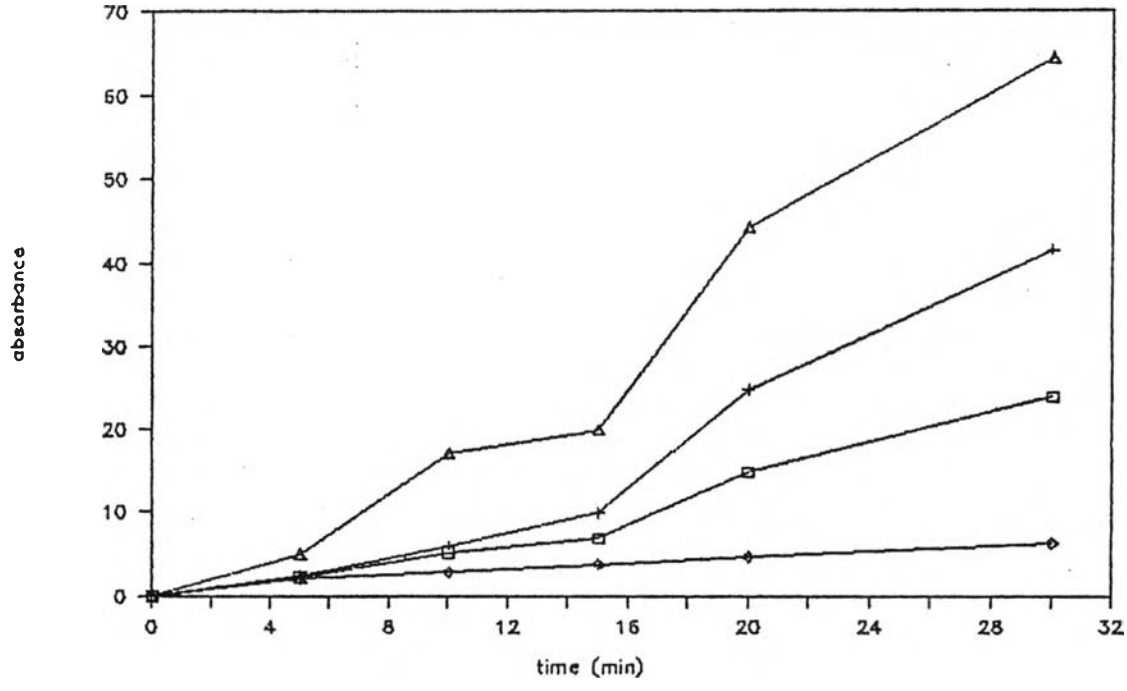


Figure 114. Dissolution Profiles of hydrochlorothiazide tablets containing 1% of disintegrant : □ D_1, + D_2, ◇ corn starch, Δ Explotab.

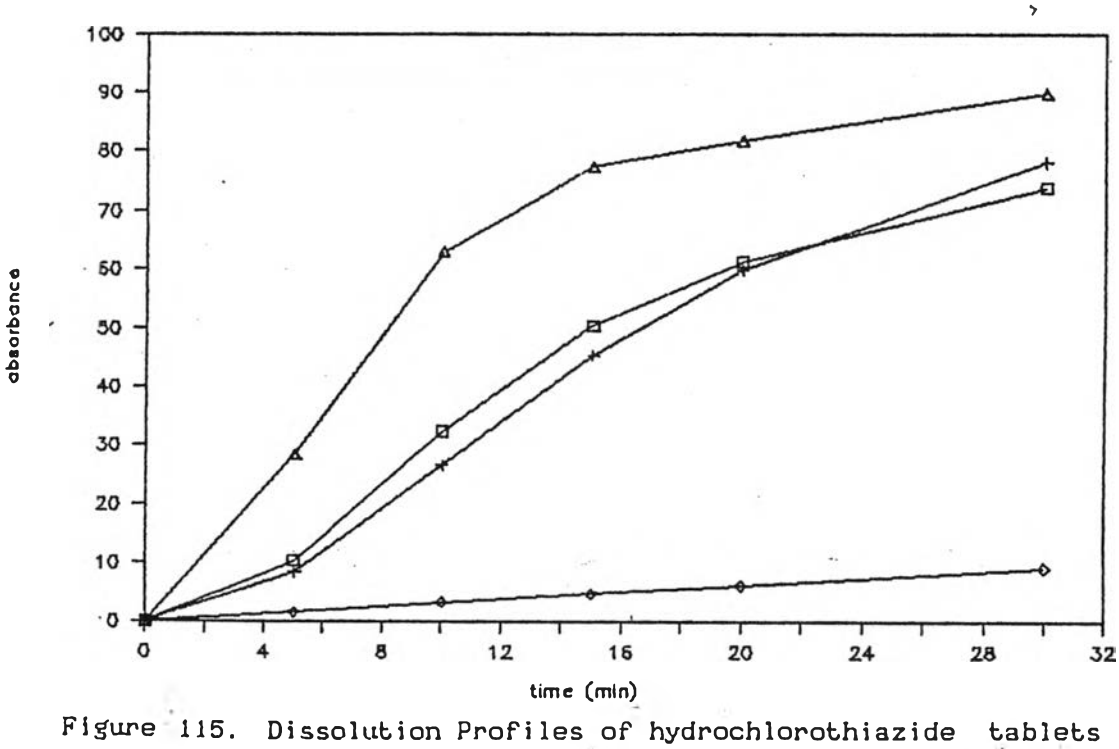


Figure 115. Dissolution Profiles of hydrochlorothiazide tablets containing 2% of disintegrant : □ D_1, + D_2, ◇ corn starch, Δ Explotab.

(g) Dissolution of Tablets

The dissolution curve of hydrochlorothiazide tablets containing different disintegrants in Ø.1 N. hydrochloric acid are presented in Figures 114-115. The highest dissolution rate was found for tablets containing Explotab(R) followed by D_1 or D_2 and corn starch. At 1% concentration, the dissolution of D_2 was higher than that containing D_1. However, at 2% level, no significant difference in efficiency between D_1 and D_2 have been observed. As concentration of disintegrant increased, the increasing in dissolution rate was obtained except for corn startch, which showed no significant difference from control formulation as shown in Figures 114-115. The results indicated that the dissolution of hydrochlorothiazide tablet containing Explotab 1 or 2% and D_1 or D_2 2% were well within acceptable limit of USP standard (not less than 60% dissolved within 30 minutes).

The Evaluation of Pyridoxine hydrochloride Tablets

Pyridoxine hydrochloride tablets prepared by direct compression using dibasic calcium phosphate dihydrate as diluent and D_1, D_2, Explotab(R) and corn starch as disintegrant were observed for their physical properties as follows : (a) weight variation (b) thickness (c) hardness (d) friability (e) content unitormity (f) disintegration time and (g) dissolution of tablets. Data from these measrements are shown in Tables 30-31 and Figures 116-117.

(a-d) Weight variation, Thickness, Hardness and Friability

The average value and standard deviation of weight, thickness and hardness for pyridoxine hydrochloride tablets are shown in Table 30. In all cases weight variation of tablets were well within the limit of USP standard. For

Table 30

Physical Properties of Pyridoxine Hydrochloride in Dibasic Calcium Phosphate Dihydrate Tablets Containing D_1, D_2, corn starch and Explotab(R) at 1 and 2% as Disintegrants.

Disintegrant	-	D_1		D_2		Corn starch		Explotab(R)	
%	-	1	2	1	2	1	2	1	2
weight (mg.) (± S.D.)	348.5 (6.1)	358.0 (1.4)	356.7 (1.3)	351.2 (1.0)	359.7 (1.5)	353.5 (1.9)	354.8 (3.3)	353.3 (1.4)	359.1 (1.8)
thickness(mm.) (± S.D.)	3.112 (0.303)	3.241 (0.008)	3.191 (0.007)	3.172 (0.014)	3.216 (0.011)	3.213 (0.009)	3.185 (0.021)	3.052 (0.672)	3.237 (0.019)
hardness(kg.) (± S.D.)	6.36 (0.73)	6.75 (0.26)	7.12 (0.59)	6.83 (0.29)	6.79 (0.35)	6.62 (0.78)	7.27 (0.62)	6.40 (0.61)	7.04 (0.62)
% friability	0.48	0.44	0.38	0.42	0.39	0.47	0.44	0.40	0.36
disintegration time (sec) (range)	>30min	172.00 (160-185)	123.67 (120-135)	190.33 (166-206)	114.17 (102-120)	>30min	>30min	113.83 (110-123)	71.67 (65-80)

thickness, the significantly difference was not found among formulations. The hardness of tablets were found to be in the range of 7 ± 1 kg. The friability of tablets were within acceptable limitted (< 1%).

(e) Content Uniformity of Tablets

The results of average content, standard deviation and percent labelled amount of pyridoxine hydrochloride tablets containing different disntegrant are shown in Table 31. In all formulations, content uniformity were well within the limit of USP standard.

(f) Disintegration time of Tablets

The disintegration time of tablets are shown in Table 30. For all cases except for corn starch formulations, disintegration time of Tablets were reduced significantly from the control formulation which showed no disintegration after 30 minutes. Explotab$^{(R)}$ showed much more effective in causing disintegration than other disintegrants. On increasing concentration of disintegrant from 1 to 2% caused disintegration time decreased signifcantly. However, it was observed that the disintegration time of D_1 containing tablets are approximately the same as those containing D_2 and the results are in agreement with the dissolution data as given in Figures 116-117.

(g) Dissolution of Tablets

The dissolution curves of pyridoxine hydrochloride tablets containing different disintegrants in dilute hydrochloric acid (1 in 100) are presented in Figures 116-117. Dissolution curve of Explotab$^{(R)}$, D_1 and D_2 formulations at 2% level were found slightly different by Explotab$^{(R)}$ formulation possesed higher rate than those containing D_1 and D_2. At 1% level no

Table 31

Content Uniformity and Percent Labelled Amount of Pyridoxine Hydrochloride Tablets Containing D_1, D_2, Corn Starch and Explotab(R) at 1 and 2% as Disintegrants.

Disintegrant		content(mg.) X ± S.D.	% labelled amount (range)
Blank		22.78±0.50	108.6 (103.6-111.5)
D_1	1%	22.41±0.97	106.7 (96.6-112.1)
	2%	21.71±0.80	103.4 (96.6-108.3)
D_2	1%	22.37±0.97	106.5 (97.7-113.5)
	2%	21.37±0.42	101.8 (99.4-106.1)
Corn Starch	1%	21.98±0.84	104.7 (99.1-111.3)
	2%	21.90±0.81	104.3 (97.5-108.3)
Explotab(R)	1%	21.07±0.63	100.3 (96.9-106.3)
	2%	21.70±0.80	103.3 (97.2-108.0)

* average from 10 tablets

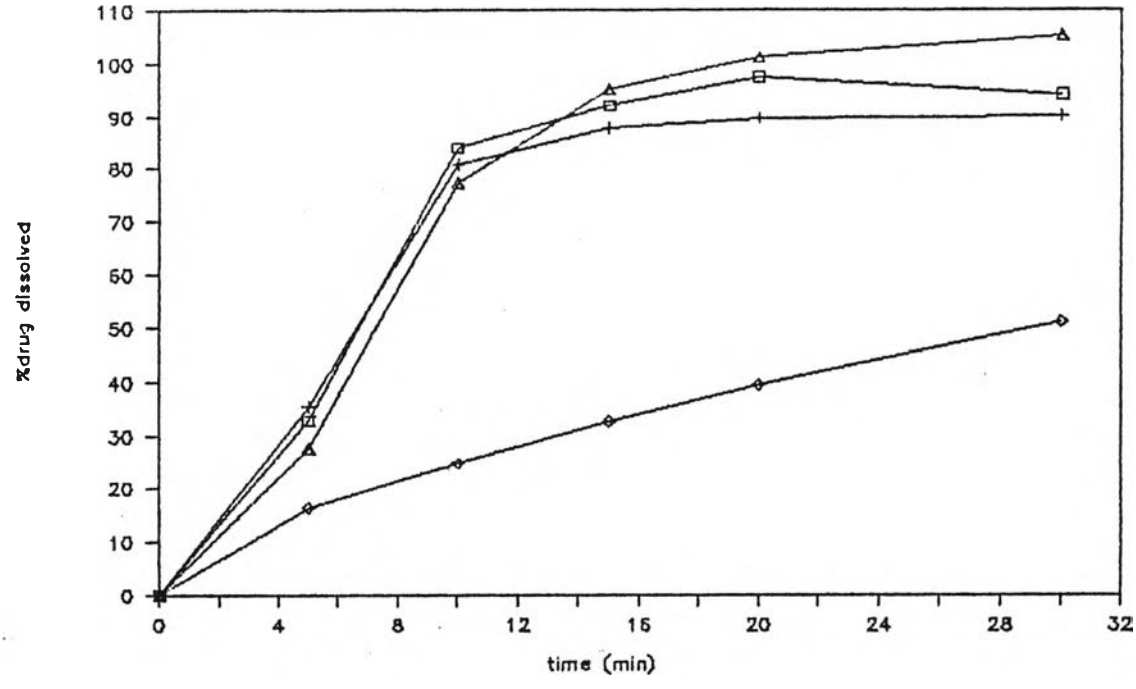


Figure 116. Dissolution Profiles of pyridoxine hydrochloride tablets containing 1% of disintegrants : ◻ D_1, + D_2, ◊ corn starch, △ Explotab.

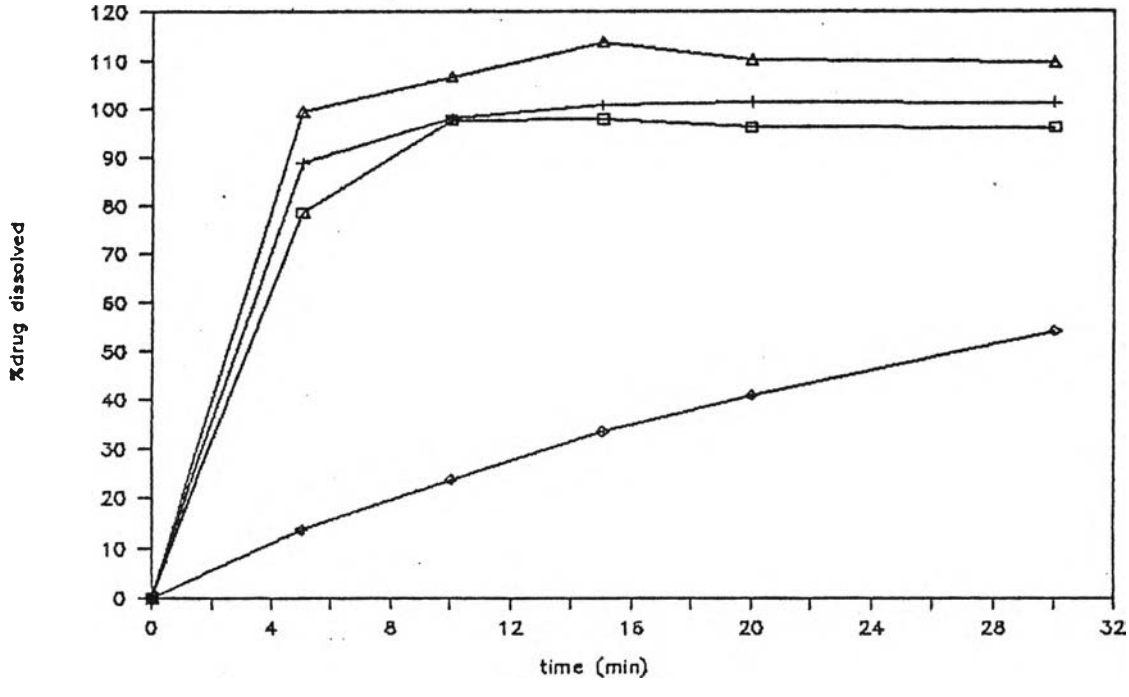


Figure 117. Dissolution Profiles of pyridoxine hydrochloride tablets containing 2% of disintegrants :◻ D_1, + D_2, ◊ corn starch, △ Explotab.

different in dissolution rate among various formulations have been observed. On increasing concentration of disintegrants from 1 to 2%, the increasing in dissolution rate could be clearly seen. In contrast, tablets containing corn starch both 1 and 2% level showed no improvement in dissolution rate as compared with control formulation.